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CEDIA® BUPRENORPHINE II APPLICATION

ORTHO CLINICAL DIAGNOSTICS VITROS® XT 7600 INTEGRATED SYSTEM, VITROS® 5600 INTEGRATED SYSTEM, AND VITROS® 4600 CHEMISTRY SYSTEM

Reference No. 10020849

Intended for the Qualitative and Semiquantitative Determination for the Presence of Buprenorphine and Its Metabolites in Human Urine at a Cutoff Concentration of 10 ng/mL

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

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 60 days.

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, and provides 118 tests.

R1 (mL) in UDxx/A	R2 (mL) in UDxx/B	Tests/pack
15	15	118

***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.

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. 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, a sample above the cubic spline prediction range, but within the System photometer range, will produce an ER error. 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, after a calibrator lot change, after performance of monthly instrument maintenance, and as required following the laboratory's quality control procedures.

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CEDIA Buprenorphine II Assay – Qualitative
Ortho Clinical Diagnostics VITROS® XT 7600 System, VITROS® 5600 System, and VITROS® 4600 System Parameters

Full Assay Name: Bup Qual Version Date: 09/12/2017

Short Assay Name: BII10 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 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

Units:

Number of Qualitative Ranges: 2

Significant Digits: 5 Precision Digits: 1

1. NEGATIVE

User Adjusted Parameters

2. POSITIVE 10 or greater

Slope: 1.0 Intercept: 0.0

Report Qualitative Result Outside of Range: Yes

CuveTip Exp Time: 35 Temp Sens : No

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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CEDIA Buprenorphine II Assay – Qualitative
Ortho Clinical Diagnostics VITROS® XT 7600 System, VITROS® 5600 System, and VITROS® 4600 System Parameters

Edit Protocol Parameters

	Step	Volume	Pack ID	Seconds	Wavelength
1.	Reagent	100 µL	UDxx /A		
2.	Incubation			0.0	
3.	Sample	14.3 µL			
4.	Incubation			304.0	
5.	Reagent	100 µL	UDxx /B		
6.	Incubation			228.0	
7.	Read				575 nm
8.	Incubation			76.0	
9.	Read				575 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: 10

(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: 0.990

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

Edit Triple Read Parameters

	Reportable Conc.	Triple Read Limit
Reportable Min.:	0	0.80
Critical Conc.:	10	8.0 %
Reportable Max.:	10000	8.0 %

Comments: N/A

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CEDIA Buprenorphine II Assay – Semiquantitative
Ortho Clinical Diagnostics VITROS® XT 7600 System, VITROS® 5600 System, and VITROS® 4600 System Parameters

Full Assay Name: Bup SemiQuant Version Date: 09/12/2017

Short Assay Name: BII Fluid Type: Urine

Assay Model Type: 2 Point Rate Template: *2Pt R1-S-R2

Cal Model Type: Cubic Spline Calibrator Bottles: 5 Reagent Reps per Cal : 2

Reagent Lot Information

On-Board Stability: 60 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

Units: ng/mL

Significant Digits: 5 Precision Digits: 1

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 10 or greater

Report Qualitative Result Outside of Range: Yes

Measuring (Reportable) 0 to 100

(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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CEDIA Buprenorphine II Assay – Semiquantitative
Ortho Clinical Diagnostics VITROS® XT 7600 System, VITROS® 5600 System, and VITROS® 4600 System Parameters

Edit Protocol Parameters

	Step	Volume	Pack ID	Seconds	Wavelength
1.	Reagent	100 µL	UDxx /A		
2.	Incubation			0.0	
3.	Sample	14.3 µL			
4.	Incubation			304.0	
5.	Reagent	100 µL	UDxx /B		
6.	Incubation			228.0	
7.	Read				575 nm
8.	Incubation			76.0	
9.	Read				575 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: 10
3	1.0	0.20	Cal Value: 20
4	1.0	0.20	Cal Value: 50
5	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

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

Edit Triple Read Parameters

	Reportable Conc.	Triple Read Limit
Reportable Min.:	0	0.80
Critical Conc.:	10	8.0 %
Reportable Max.:	100	8.0 %

Comments: N/A

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