DRI® Oxycodone Assay for SYNCHRON Systems Application for: BECKMAN COULTER* UniCel* DxC and SYNCHRON* Systems

Beckman Coulter Reagent Part Number A53730

Intended for the qualitative or semi-quantitative determination of Oxycodone and its metabolite Oxymorphone in human urine.

For In Vitro Diagnostic Use 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 storage, quality control, and additional performance data.

Ordering Information

The following materials are available from your local Beckman Coulter Representative.

Item	Beckman Coulter Reorder Number
DRI® Oxycodone Reagent Kit	A53730
DRI® Negative Calibrator	A44121
DRI® Oxycodone 100 ng/mL Calibrator	A53734
DRI® Oxycodone 300 ng/mL Calibrator	A53738
DRI® Oxycodone 500 ng/mL Calibrator	A53733
DRI® Oxycodone 1000 ng/mL Calibrator	A53736
DRI® Oxycodone Controls (225 and 375 ng/mL)	A53731
User-Defined Reagent Cartridge (pkg. of 12)	442835

Technical Support

For Technical Support, please contact your local Beckman Coulter Representative.

Reagent Storage

Refer to the package insert for information on reagent storage.

Note:
It is not recommended to leave the reagent on-board for more than 60 days.

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Instructions For Use

Analyzer Operating Procedures

Refer to the operator's manuals for information on analyzer operation. Reagents are supplied ready to use, Antibody/Substrate Reagent R1 and Enzyme Conjugate Reagent R2. Dispense one bottle of each R1 and R2 into appropriate compartments of a User Defined Cartridge (PN 442835), using care to avoid contamination.

The following table outlines reagent preparation.

	User Defined Cartridge	
DRI Oxycodone for SYNCHRON and UniCel Systems	Compartment A	Compartment B
Antibody/Substrate Reagent R1	One Bottle (30 mL)	
Enzyme Conjugate Reagent R2		One Bottle (7 mL)

Calibrator Information

Refer to the package insert for calibration information. The UniCel DxC, SYNCHRON LX and CX analyzers require calibration to be performed every 14 days or as indicated by control recovery.

Recommended Controls

Item	Beckman Coulter Reorder Number
DRI® Oxycodone Controls (225 and 375 ng/mL)	A53731

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Application Parameters

Parameters The following tables outline the DRI Oxycodone Assay chemistry parameters for **qualitative** mode on the UniCel DxC and SYNCHRON LX analyzers.

Number **[*]** Chem **[OXYX]**

Chemistry Parameters			Page 1 of 3
Reaction Type	**[Rate 1]**		
Units	**[mA/min]**		
Precision	**[X.X]**		
Reaction Direction	**[Positive]**		
Math Model	**[DAT]**		
Primary Wavelength	**[340]**		
Secondary Wavelength	**[650]**		
Calculation Factor	**[1000]**		
No. of Calibrators	**[3]**		
Setpoints	1 **[0.0]**	4 **[ ]**	
	2 **[300.0]**	5 **[ ]**	
	3 **[1000.0]**	6 **[ ]**	
Cal Time Limit	**[User Defined*] hours**		
Cal Save	**[√]**		

Processing Parameters			Page 2 of 3
First Inject	Component	**[A]**	
	Dispense Volume	**[200] µL**	
Second Inject	Component	**[None]**	
	Dispense Volume	**[ ]**	
	Inject Time	**[ ] sec**	
Third Inject	Component	**[B]**	
	Dispense Volume	**[50] µL**	
	Inject Time	**[48] sec**	
Sample Volume	**[15] µL**		
ORDAC Volume	**[ ] µL**		
<F2 Dilute>			
Neat Sample Volume	**[ ]**		
Diluent§ Volume	**[ ]**		
Dilution Factor	**0.0** *(automatic)*		
Sample Diluent	**[√]** UDR Component A		
Blank	Start Read	**[-83] sec**	
	End Read	**[-20] sec**	
Initial (DxC only)	Start Read	**[96] sec**	
	End Read	**[144] sec**	
Reaction 1	Start Read	**[96] sec**	
	End Read	**[144] sec**	
Reaction 2	Start Read	**[ ] sec**	
	End Read	**[ ] sec**	

Error Detection Limits			Page 3 of 3
Blank	ABS Low/High Limits	**[-1.500]/[2.200]**	
	Rate Low/High Limits	**[-1.500]/[2.200]**	
	Mean Deviation	**[2.200]**	
Reaction 1	ABS Low/High Limits	**[-1.500]/[2.200]**	
	Rate Low/High Limits	**[-1.500]/[2.200]**	
	Mean Deviation	**[2.200]**	
Reaction 2	ABS Low/High Limits	**[-1.500]/[2.200]**	
	Rate Low/High Limits	**[-1.500]/[2.200]**	
	Mean Deviation	**[2.200]**	
Substrate Depletion			
	Initial Rate	**[99.999]**	
	Delta ABS	**[2.200]**	
Multipoint Span			
	1-2	**[0.001]**	**[ ]**
	2-3	**[0.001]**	**[ ]**
		[ ]	**[ ]**
Usable Result Range			
	Low Limit	**[0.000]**	
	High Limit	**[99999.999]**	
ORDAC			
	Low Limit	**[0.000]**	
	High Limit	**[99999.999]**	

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Application Parameters, continued

Parameters

The following tables outline the DRI Oxycodone Assay chemistry parameters for **qualitative** mode on the SYNCHRON CX analyzer.

Number **[*]** Chem **[OXYX]**

Chemistry Parameters			Page 1 of 3
Reaction Type		**[Rate 1]**	
Units		**[ng/mL]**	
Precision		**[X.X]**	
Reaction Direction		**[Positive]**	
Calculation Factor		**[0]**	
Math Model		**[Linear]**	
Primary Wavelength		**[340]**	
Secondary Wavelength		**[650]**	
No. of Calibrators		**[2]**	
Setpoints	1	**[0.0]**	4 **[ ]**
	2	**[300.0]**	5 **[ ]**
	3	**[ ]**	6 **[ ]**
Cal Time Limit		**[User Defined*] hours**	

Processing Parameters		Page 2 of 3
First Inject	Component	**[A]**
	Dispense Volume	**[200] µL**
Second Inject	Component	**[B]**
	Dispense Volume	**[50] µL**
	Inject Time	**[368] sec**
Third Inject	Component	**[ ]**
	Dispense Volume	**[ ] µL**
	Inject Time	**[ ] sec**
Sample Volume		**[15] µL**
Reagent Blank	Start Read	**[237] sec**
	End Read	**[300] sec**
Reaction	Start Read	**[96] sec**
	End Read	**[144] sec**
Usable Range:	Lower Limit	**[0.00]**
	Upper Limit	**[99999.0]**

Error Detection Limits		Page 3 of 3
Reagent Blank	ABS Low/High Limits	**[-1.500]/[1.500]**
Reaction	ABS Low/High Limits	**[-1.500]/[1.500]**
Substrate Depletion		
	Initial Rate	**[99.999]**
	Delta ABS	**[1.500]**
Multipoint Span		
	1-2 [0.001]	

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Application Parameters, continued

Parameters The following tables outline the DRI Oxycodone Assay chemistry parameters for **semi-quantitative** mode on the UniCel DxC and SYNCHRON LX analyzers.

Number **[*]** Chem **[OXYX]**

Chemistry Parameters			Page 1 of 3
Reaction Type	**[Rate 1]**		
Units	**[ng/mL]**		
Precision	**[X.X]**		
Reaction Direction	**[Positive]**		
Math Model	**[1]**		
Primary Wavelength	**[340]**		
Secondary Wavelength	**[650]**		
Calculation Factor	**[1.000]**		
No. of Calibrators	**[5]**		
Setpoints	1 **[0.0]**	4 **[500.0]**	
	2 **[100.0]**	5 **[1000.0]**	
	3 **[300.0]**	6 **[ ]**	
Cal Time Limit	**[User Defined*] hours**		
Cal Save	**[√]**		

Processing Parameters			Page 2 of 3
First Inject	Component	**[A]**	
	Dispense Volume	**[200] µL**	
Second Inject	Component	**[None]**	
	Dispense Volume	**[ ]**	
	Inject Time	**[ ] sec**	
Third Inject	Component	**[B]**	
	Dispense Volume	**[50] µL**	
	Inject Time	**[48] sec**	
Sample Volume	**[15] µL**		
ORDAC Volume	**[ ] µL**		
<F2 Dilute>			
Neat Sample Volume	**[ ]**		
Diluent[§] Volume	**[ ]**		
Dilution Factor	**0.0** *(automatic)*		
Sample Diluent	**[√]** UDR Component A		
Blank	Start Read	**[-83] sec**	
	End Read	**[-20] sec**	
Initial (DxC only)	Start Read	**[96] sec**	
	End Read	**[144] sec**	
Reaction 1	Start Read	**[96] sec**	
	End Read	**[144] sec**	
Reaction 2	Start Read	**[ ] sec**	
	End Read	**[ ] sec**	

Error Detection Limits			Page 3 of 3
Blank	ABS Low/High Limits	**[-1.500]/[2.200]**	
	Rate Low/High Limits	**[-1.500]/[2.200]**	
	Mean Deviation	**[2.200]**	
Reaction 1	ABS Low/High Limits	**[-1.500]/[2.200]**	
	Rate Low/High Limits	**[-1.500]/[2.200]**	
	Mean Deviation	**[2.200]**	
Reaction 2	ABS Low/High Limits	**[-1.500]/[2.200]**	
	Rate Low/High Limits	**[-1.500]/[2.200]**	
	Mean Deviation	**[2.200]**	
Substrate Depletion			
	Initial Rate	**[99.999]**	
	Delta ABS	**[2.200]**	
Multipoint Span			
	1-2 [0.043]	**4-5 [0.021]**	
	2-3 [0.057]	**5-1 [0.145]**	
	3-4 [0.023]	**[ ]**	
Usable Result Range			
	Low Limit	**[0.000]**	
	High Limit	**[99999.999]**	
ORDAC			
	Low Limit	**[0.000]**	
	High Limit	**[99999.999]**	

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Application Parameters, continued

Parameters

The following tables outline the DRI Oxycodone Assay chemistry parameters for **semi-quantitative** mode on the SYNCHRON CX analyzer.

Number **[*]** Chem **[OXYX]**

Chemistry Parameters				Page 1 of 3
Reaction Type	**[Rate 1]**			
Units	**[ng/mL]**			
Precision	**[X.X]**			
Reaction Direction	**[Positive]**			
Calculation Factor	**[0]**			
Math Model	**[1]**			
Primary Wavelength	**[340]**			
Secondary Wavelength	**[650]**			
No. of Calibrators	**[5]**			
Setpoints	1	**[0.0]**	4	**[500.0]**
	2	**[100.0]**	5	**[1000.0]**
	3	**[300.0]**	6	**[ ]**
Cal Time Limit	**[User Defined*] hours**			

Processing Parameters		Page 2 of 3
First Inject	Component	**[A]**
	Dispense Volume	**[200] µL**
Second Inject	Component	**[B]**
	Dispense Volume	**[50] µL**
	Inject Time	**[368] sec**
Third Inject	Component	**[ ]**
	Dispense Volume	**[ ] µL**
	Inject Time	**[ ] sec**
Sample Volume	**[15] µL**	
Reagent Blank	Start Read	**[237] sec**
	End Read	**[300] sec**
Reaction	Start Read	**[96] sec**
	End Read	**[144] sec**
Usable Range	Lower Limit	**[0.00]**
	Upper Limit	**[99999.00]**

Error Detection Limits		Page 3 of 3
Reagent Blank	ABS Low/High Limits	**[-1.500]/[1.500]**
Reaction	ABS Low/High Limits	**[-1.500]/[1.500]**
Substrate Depletion		
	Initial Rate	**[99.999]**
	Delta ABS	**[1.500]**
Multipoint Span:		
1-2 [0.041]	4-5 [0.009]	
2-3 [0.071]	5-1 [0.169]	
3-4 [0.026]		

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Results and Data Interpretation

Performance Data

Refer to the DRI Oxycodone reagent package insert for additional information on results and data interpretation.

Instrument Precision

The within-run and total run precision, evaluated with packaged reagents, controls, and calibrators, yielded the following results (n=120). Properly operating UniCel and SYNCHRON systems should exhibit precision values comparable to the following. Instruments operated and maintained according to the manufacturer's instructions should exhibit a Qualitative within-run coefficient of variation of ≤ 2% for all sample levels.

Qualitative Precision									
Instrument:	**CX4**			**DxC600**			**LX20**		
Rate	Negative control 225 ng/mL	Cutoff Calibrator 300 ng/mL	Positive Control 375 ng/mL	Negative control 225 ng/mL	Cutoff Calibrator 300 ng/mL	Positive Control 375 ng/mL	Negative control 225 ng/mL	Cutoff Calibrator 300 ng/mL	Positive Control 375 ng/mL
Mean (mA/min)	373.0	399.3	427.0	410.3	440.2	471.2	400.9	430.2	459.9
Within Run Precision									
SD (mA/min)	1.9	1.7	1.8	2.1	2.1	2.1	2.9	3.2	3.8
%CV	**0.5**	**0.4**	**0.4**	**0.5**	**0.5**	**0.4**	**0.7**	**0.7**	**0.8**
Total Run Precision									
SD (mA/min)	3.5	3.8	4.0	4.5	5.2	5.0	5.4	6.0	5.8
%CV	**0.9**	**0.9**	**0.9**	**1.1**	**1.2**	**1.1**	**1.3**	**1.4**	**1.3**

Semi-quantitative Precision									
Instrument:	**CX4**			**DxC600**			**LX20**		
Concentration	Negative control 225 ng/mL	Cutoff Calibrator 300 ng/mL	Positive Control 375 ng/mL	Negative control 225 ng/mL	Cutoff Calibrator 300 ng/mL	Positive Control 375 ng/mL	Negative control 225 ng/mL	Cutoff Calibrator 300 ng/mL	Positive Control 375 ng/mL
Mean (ng/mL)	228.7	295.2	376.8	227.2	293.2	377.9	230.3	294.3	376.8
Within Run Precision									
SD (ng/mL)	3.8	4.4	7.0	4.3	5.1	7.8	6.4	7.9	10.6
%CV	**1.7**	**1.5**	**1.9**	**1.9**	**1.7**	**2.1**	**2.8**	**2.7**	**2.8**
Total Run Precision									
SD (ng/mL)	5.3	6.8	9.5	7.6	9.9	14.3	9.7	13.5	18.5
%CV	**2.3**	**2.3**	**2.5**	**3.4**	**3.4**	**3.8**	**4.2**	**4.6**	**4.9**

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Results and Data Interpretation, continued

Cross Reactivity

Oxycodone compounds and Oxycodone structurally-related compounds were tested for cross-reactivity. The concentrations for the cross-reactants are listed in the tables below.

Oxycodone Compounds that tested Positive

Cross-Reactant	Tested Concentration (ng/mL)
Cutoff Calibrator	**300 ng/mL**
Oxymorphone	300
Noroxycodone	50,000
Noroxymorphone	500,000

Oxycodone Structurally Related Compounds that tested Negative

Instruments	UniCel DxC600, SYNCHRON LX20, CX4
Cross-Reactant	**Tested Concentration (µg/mL)**
Cutoff Calibrator	**300 ng/mL**
6-Acetyl-Morphine	50
Codeine	500
Dihydrocodeine	100
Heroin	300
Hydrocodone	75
Hydromorphone	30
Levorphanol	200
Morphine	350
Morphine-3-glucoronide	900
Naloxone	200
Naltrexone	500
Norcodeine	1000
Normorphine	1000

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Results and Data Interpretation, continued

Method Comparison

A total of 149 clinical samples were tested in **qualitative and semi-quantitative** modes on the UniCel DxC600, SYNCHRON LX20 and CX4, and compared to the results by GC/MS. The data were analyzed and presented in the tables below.

Qualitative

		GC/MS -	GC/MS +
CX4	-	78	5*
	+	4*	62
Positive Sample Agreement:			92.5%
Negative Sample Agreement:			95.1%
Total Sample Agreement:			94.0%

		GC/MS -	GC/MS +
DxC600	-	78	3*
	+	4*	64
Positive Sample Agreement:			95.5%
Negative Sample Agreement:			95.1%
Total Sample Agreement:			95.3%

		GC/MS -	GC/MS +
LX20	-	77	0
	+	5*	67
Positive Sample Agreement:			100%
Negative Sample Agreement:			93.9%
Total Sample Agreement:			96.6%

Semi-quantitative:

		GC/MS -	GC/MS +
CX4	-	78	2*
	+	4*	65
Positive Sample Agreement:			97.0%
Negative Sample Agreement:			95.1%
Total Sample Agreement:			96.0%

		GC/MS -	GC/MS +
DxC600	-	78	0
	+	4*	67
Positive Sample Agreement:			100%
Negative Sample Agreement:			95.1%
Total Sample Agreement:			97.3%

		GC/MS -	GC/MS +
LX20	-	76	0
	+	6*	67
Positive Sample Agreement:			100%
Negative Sample Agreement:			92.7%
Total Sample Agreement:			96.0%

* Of the 149 total clinical samples confirmed by GC/MS (Gas Chromatography / Mass Spectrometry), nine of the discrepant samples were between 225 ng/mL and 375 ng/mL (±25% of cutoff concentration). Prior to GC/MS screening, an enzymatic hydrolysis pre-treatment was performed.

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Additional Information

Important	Information on sample preparation, expected values, quality control, as well as warnings and precautions related to the use of this reagent may be obtained from the package insert. Instrument operating instructions are contained in the UniCel DxC Systems Instructions For Use (IFU) Manual, SYNCHRON LX Operations Manual or SYNCHRON CX Operating Instructions. Since Beckman Coulter does not manufacture the reagent or perform quality control or other tests on individual lots, Beckman Coulter cannot be responsible for the quality of the data obtained which is caused by performance of the reagent, any variation between lots of reagent, or protocol changes by the manufacturer.
Shipping Damage	If damaged product is received, notify your Beckman Coulter Clinical Support Center.

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