

DRI[®] OXYCODONE APPLICATION BECKMAN COULTER DxC 700 AU



Beckman Coulter Reagent REF 100248

Intended for the qualitative and semiquantitative determination of oxycodone in human urine. This application pertains only to the 300 ng/mL when analyzing in qualitative mode.



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.

Ordering Information

Item	Size	Beckman Coulter Reorder Number
DRI Oxycodone Assay	1 x 68 mL	100248
DRI Negative Calibrator	1 x 10 mL	1664
DRI Oxycodone 100 ng/mL Calibrator	1 x 10 mL	100250
DRI Oxycodone 300 ng/mL Calibrator	1 x 10 mL	100251
DRI Oxycodone 500 ng/mL Calibrator	1 x 10 mL	100252
DRI Oxycodone 1000 ng/mL Calibrator	1 x 10 mL	100253
DRI Oxycodone 100 ng/mL Control	1 x 10 mL	100254
DRI Oxycodone 300 ng/mL Control	1 x 10 mL	100255
AU Bottle	20 X 30 mL	63094

Technical Support

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

Reagent Storage

Refer to the package insert for information on reagent storage.

Continued on next page

Instructions For Use

Procedure for Analyzer Refer to the operator's manuals for information on analyzer operation. Refer to the package insert for complete reagent preparation.

Prior to pouring into AU bottles, allow the reagent to equilibrate for 15 minutes at refrigerated temperature (2 to 8°C). Dispense R1 reagent and R2 reagent into appropriate AU bottles as shown in the table below:

DRI Oxycodone Assay Kit	AU Reagent Bottle	
	R1 Compartment	R2 Compartment
Antibody/Substrate Reagent R1	One Bottle (30 mL)	
Enzyme Conjugate Reagent R2		One Bottle (30 mL)

Warning: These reagents have to be programmed to fixed positions. Do not use the Thermo reagent bottles directly on the AU analyzer.

Results and Data Interpretation Results for samples will be printed in ng/mL.

Specimen Preparation Refer to the package insert for the complete specimen preparation. The product insert can be found at the Thermo Fisher Scientific website:

www.thermofisher.com

Calibration Use the DRI Oxycodone calibrators. The calibrators are liquid and ready-to-use.



DRI Oxycodone Assay
Beckman Coulter System Parameters, DxC 700 AU
Qualitative (300 ng/mL Cutoff Only)

General	LIH	ISE	Calculated Test	Range
Test Name: # <input type="text"/> Type: Urine Operation: Yes				
Sample Volume	<input type="text" value="10.5"/> μL	Dilution <input type="text" value="0"/> μL	OD Limit	
Pre-Dilution Rate	<input type="text" value="1"/>		Min. OD <input type="text" value="-2.0000"/> Max OD <input type="text" value="3.0000"/>	
Reagent Volume	R1 (R1-1) <input type="text" value="87"/> μL	Dilution <input type="text" value="0"/> μL	Reagent OD Limit 1 st Low <input type="text" value="-2.0000"/> High <input type="text" value="3.0000"/>	
	R1-2 <input type="text"/> μL	Dilution <input type="text"/> μL	Last Low <input type="text" value="-2.0000"/> High <input type="text" value="3.0000"/>	
	R2 (R2-1) <input type="text" value="87"/> μL	Dilution <input type="text" value="0"/> μL	Analytical Measuring Range Low <input type="text" value="-9999"/> High <input type="text" value="9999"/>	
Common Reagent	Type <input type="text" value="None"/>	Name <input type="text" value="None"/>	Correlation Factor A <input type="text" value="1"/> B <input type="text" value="0"/>	
Wavelength	Pri <input type="text" value="340"/> nm	Sec <input type="text" value="410"/> nm	Manufacturer Factor A <input type="text" value="1"/> B <input type="text" value="0"/>	
Method	<input type="text" value="FIXED"/>			
Reaction Slope	<input type="text" value="+"/> \downarrow		Onboard Stability Period <input type="text" value="30"/> Day <input type="text" value="0"/> Hour	
Measuring Point-1	1st <input type="text" value="17"/> Last <input type="text" value="21"/>		LIH Influence Check <input type="text" value="No"/> \downarrow	
Measuring Point-2	1st <input type="text"/> Last <input type="text"/>		Lipemia <input type="text" value="+"/> \downarrow	
Linearity Limit	<input type="text"/> %		Icterus <input type="text" value="+"/> \downarrow	
Lag Time Check	<input type="text" value="No"/> \downarrow		Hemolysis <input type="text" value="+"/> \downarrow	

General	LIH	ISE	Calculated Test	Range
Test Name: # <input type="text"/> Type: Urine				
Value/Flag	<input type="text" value="Flag"/>	Level	Low <input type="text" value="-999999"/> High <input type="text" value="300"/>	
Specific Ranges				
	Sex	From Year	Month	To Year
				Month
<input type="checkbox"/> 1:	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>
<input type="checkbox"/> 2:	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>
<input type="checkbox"/> 3:	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>
<input type="checkbox"/> 4:	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>
<input type="checkbox"/> 5:	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>
<input type="checkbox"/> 6:	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>
7:	Standard demographics			<input type="text" value="#"/>
8:	Not within expected values			<input type="text" value="#"/>
Critical Limits	Low <input type="text" value="#"/>	High <input type="text" value="#"/>	Unit <input type="text" value="ng/mL"/>	Decimal Places <input type="text" value="0"/>

User Defined

DRI Oxycodone Assay
Beckman Coulter System Parameters, DxC 700 AU
Qualitative (300 ng/mL Cutoff Only), *continued*

Calibrators	General	ISE	
Test Name: # ▼		Type: Urine ▼	
<input type="checkbox"/> Use Serum Cal.			
Calibration Type: <input type="text" value="AB"/> ▼		Formula: <input type="text" value="Y=AX+B"/> ▼	
		Counts: <input type="text" value="2"/>	
<Calibrator Parameters>			
			Slope Check <input type="text"/> ▼
	Calibrator	OD	Conc
			Range
			Low High
Point-1	# ▼		300
Point-2	▼		-999999 999999
Point-3	▼		
Point-4	▼		
Point-5	▼		
Point-6	▼		
Point-7	▼		
MB Type Factor <input type="text"/>		1-Point Calibration Point <input type="text" value="None"/> ▼	
		<input type="checkbox"/> with Conc-0	
		Stability	
		Reagent Blank <input type="text" value="#"/> Day <input type="text" value="0"/> Hour	
		Calibration <input type="text" value="#"/> Day <input type="text" value="0"/> Hour	
		Interval (RB) <input type="text"/> ▼	
		Interval (ACAL) <input type="text"/> ▼	
		<input type="checkbox"/> Allowable Range Check <input type="checkbox"/> Reagent Blank <input type="text"/> <input type="checkbox"/> Calibration <input type="text"/> Advanced Calibration Operation <input type="text" value="No"/> ▼	

User Defined



DRI Oxycodone Assay Beckman Coulter System Parameters, DxC 700 AU – Semiquantitative

General	LIH	ISE	Calculated Test	Range
Test Name: # ▼ Type: Urine ▼ Operation: Yes ▼				
Sample Volume	<input type="text" value="10.5"/> µL	Dilution <input type="text" value="0"/> ▼ µL	OD Limit	
Pre-Dilution Rate	<input type="text" value="1"/> ▼		Min. OD <input type="text" value="-2.0000"/> Max OD <input type="text" value="3.0000"/>	
Reagent Volume	R1 (R1-1) <input type="text" value="87"/> µL	Dilution <input type="text" value="0"/> µL	Reagent OD Limit 1 st	Low <input type="text" value="-2.0000"/> High <input type="text" value="3.0000"/>
	R1-2 <input type="text"/> µL	Dilution <input type="text"/> µL	Last	Low <input type="text" value="-2.0000"/> High <input type="text" value="3.0000"/>
	R2 (R2-1) <input type="text" value="87"/> µL	Dilution <input type="text" value="0"/> µL	Analytical Measuring Range	Low <input type="text" value="-9999"/> High <input type="text" value="9999"/>
Common Reagent	Type <input type="text" value="None"/>	Name <input type="text" value="None"/>	Correlation Factor	A <input type="text" value="1"/> B <input type="text" value="0"/>
Wavelength	Pri <input type="text" value="340"/> ▼ nm	Sec <input type="text" value="410"/> ▼ nm	Manufacturer Factor	A <input type="text" value="1"/> B <input type="text" value="0"/>
Method	<input type="text" value="FIXED1"/> ▼			
Reaction Slope	<input type="text" value="+"/> ▼		Onboard Stability Period <input type="text" value="30"/> Day <input type="text" value="0"/> Hour	
Measuring Point-1	1st <input type="text" value="17"/> Last <input type="text" value="21"/>		LIH Influence Check <input type="text" value="No"/> ▼	
Measuring Point-2	1st <input type="text"/> Last <input type="text"/>		Lipemia <input type="text" value="+"/> ▼	
Linearity Limit	<input type="text"/> %		Icterus <input type="text" value="+"/> ▼	
Lag Time Check	<input type="text" value="No"/> ▼		Hemolysis <input type="text" value="+"/> ▼	

General	LIH	ISE	Calculated Test	Range
Test Name: # ▼ Type: Urine ▼				
Value/Flag	<input type="text" value="Value"/>	Level	Low <input type="text" value="-999999"/> High <input type="text" value="999999"/>	
Specific Ranges				
	Sex	Year	From	Month
			Year	To
			Year	Month
			Other Type	Low
				High
<input type="checkbox"/> 1:	<input type="text" value="#"/> ▼	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>
<input type="checkbox"/> 2:	<input type="text" value="#"/> ▼	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>
<input type="checkbox"/> 3:	<input type="text" value="#"/> ▼	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>
<input type="checkbox"/> 4:	<input type="text" value="#"/> ▼	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>
<input type="checkbox"/> 5:	<input type="text" value="#"/> ▼	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>
<input type="checkbox"/> 6:	<input type="text" value="#"/> ▼	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>
7:	Standard demographics			<input type="text" value="#"/>
8:	Not within expected values			<input type="text" value="#"/>
Critical Limits	Low <input type="text" value="#"/>	High <input type="text" value="#"/>	Unit <input type="text" value="ng/mL"/>	Select <input type="text" value="1"/>

User Defined

DRI Oxycodone Assay
Beckman Coulter System Parameters, DxC 700 AU – Semiquantitative, *continued*

Calibrators	General	ISE			
Test Name: # Type: Serum					
<input type="checkbox"/> Use Serum Cal.					
Calibration Type: 5AB Formula: POLYGONAL Counts: 2					
<Calibrator Parameters>			Slope Check: +		
	Calibrator	OD	Conc	Range	
				Low	High
Point-1	#		0	-2.00	3.00
Point-2	#		100	-2.00	3.00
Point-3	#		300	-2.00	3.00
Point-4	#		500	-2.00	3.00
Point-5	#		1000	-2.00	3.00
Point-6					
Point-7					
MB Type Factor:		1-Point Calibration Point: None		<input type="checkbox"/> with Conc-0	
Stability					
		Reagent Blank	#	Day	0 Hour
		Calibration	#	Day	0 Hour

User Defined

Additional Information

Important

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

Please notify your Beckman Coulter Technical Support Center if this product is received damaged.

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