

DRI[®] OXYCODONE APPLICATION BECKMAN COULTER DxC 500 AU



Beckman Coulter Reagent REF 100248

This Application is Intended for the Qualitative and Semiquantitative Determination of Oxycodone 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.

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.

Continued on next page

Reagent Storage

Refer to the package insert for information on reagent storage.

Analyzer Procedure

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:

	AU Reagent Bottle	
DRI Oxycodone Assay Kit	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 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. Refer to the package insert for the concentration of each calibrator.

Reagent Name: DRI Oxycodone Assay (Qualitative- 100 ng/mL Cutoff Only) REF 100248
DxC 500 AU Urine Settings Calibrator Name DRI Oxycodone Calibrator REF 100250

Reagent ID 557

TEST CONFIGURATION & CHEMISTRY DETAILS

Assay Name	Test	Rev	Discipline	Chemistry
Test ID	<input type="text" value="OXY100"/>		Calculated Result	<input type="checkbox"/>
LIS Code	<input type="text" value="OXY100"/>		Result Type	<input type="text" value="Qualitative"/>
UNITS AND RANGE SETTINGS				
Use Settings from	<input type="text" value="None"/>	Units	<input type="text" value="None"/>	Decimal Places
				<input type="text" value="x"/>
Test Kind	<input type="text" value="General"/>	Revision	<input type="text" value="01"/>	<input checked="" type="checkbox"/> Multi Reagent Switch
Reagent Name	<input type="text" value="OXY"/>	Reagent ID	<input type="text" value="557"/>	<input type="checkbox"/> FSE Test
ABB Name	<input type="text" value="OXY1G"/>	Parameter Long Name	<input type="text" value="Oxycodone 100 (Q) 100248 OXY1G Urine"/>	
Region	<input checked="" type="checkbox"/> US	<input checked="" type="checkbox"/> OUS	<input checked="" type="checkbox"/> AP	<input type="checkbox"/> JP
			<input checked="" type="checkbox"/> EU	<input type="checkbox"/> Other

GENERAL PARAMETERS

SAMPLE VOLUME	Sample Volume <input type="text" value="14.0"/> μL	Dilution <input type="text" value="0"/> μL	REACTION OD LIMIT	Low <input type="text" value="-2.0000"/>	High <input type="text" value="3.0000"/>
	Predilution Rate <input type="text" value="1"/>		REACTION BLANK OD LIMIT	First: Low <input type="text" value="-2.0000"/>	High <input type="text" value="3.0000"/>
REAGENT VOLUME	R1-1 <input type="text" value="87"/> μL	Dilution <input type="text" value="0"/> μL		Last: Low <input type="text" value="-2.0000"/>	High <input type="text" value="3.0000"/>
	R2-1 <input type="text" value="87"/> μL	Dilution <input type="text" value="0"/> μL	ANALYTICAL MEASURING RANGE	Low <input type="text" value="0.00"/>	High <input type="text" value="1000.00"/>
WAVELENGTH	Primary <input type="text" value="340"/> nm	Secondary <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"/>		REAGENT ONBOARD STABILITY	<input type="text" value="31"/> Days	<input type="text" value="0"/> Hours
REACTION SLOPE	<input type="text" value="+"/>		LIH INFLUENCE CHECK	<input type="checkbox"/> Perform LIH check	
MEASURING POINT	Point 1: First <input type="text" value="17"/>	Last <input type="text" value="21"/>	Lipemia	<input type="text" value="+"/> <input type="text" value="▼"/>	
	Point 2: First <input type="text"/>	Last <input type="text"/>	Icterus	<input type="text" value="+"/> <input type="text" value="▼"/>	
Linearity Limit	<input type="text"/>	%	Hemolysis	<input type="text" value="+"/> <input type="text" value="▼"/>	
Lag Time Check	<input type="checkbox"/> Perform Lag Time Check				

CALIBRATION PARAMETERS

Base Unit	Decimal Place	Unit 1	Factor 1	Unit 2	Factor 2	Unit 3	Factor 3	Unit 4	Factor 4
None ▼	0 ▼	None ▼	0	None ▼	0	None ▼	0	None ▼	0

CALIBRATOR SPECIFIC

Calibration Type

Counts

Formula

MB Factor

Calibrator Name Add

Positive Cutoff

SLOPE CHECK
 Slope Check Number of Levels

CALIBRATION OD AND CONCENTRATION PARAMETERS

Use highest calibrator for Upper AMR

	Calibrator Name	Conc	Factor Range Low	Factor Range High
Point 1	OXY CAL-2	100	-999999	99999
Point 2				
Point 3				
Point 4				
Point 5				
Point 6				
Point 7				

STABILITY AND INTERVAL

Reagent Blank Stability Days Hours
 Calibration Stability Days Hours

Interval

OD DELTA CHECK

Reagent Blank
 Calibration

PROZONE CHECK PARAMETERS

Logic Check 1

Check Points
 Point 1
 Point 2
 Point 3

Decision Values
 Value 1
 Value 2
 Value 3

Limit Points
 Limit 1
 Limit 2

Check Pattern
 Pattern

Logic Check 2

Check Points
 Point 1
 Interval

Limit Points
 Limit 1
 Limit 2

Logic Check 3

Check Points
 Point 1
 Interval

Limit Points
 Limit 1
 Limit 2

Decision Values
 Value 1
 Value 2

Reagent Name: DRI Oxycodone Assay (Qualitative- 300 ng/mL Cutoff Only) REF 100248
DxC 500 AU Urine Settings Calibrator Name DRI Oxycodone Calibrator REF 100251

Reagent ID 557

TEST CONFIGURATION & CHEMISTRY DETAILS

Assay Name	Test	Rev	Discipline	Chemistry
Test ID	<input type="text" value="OXY300"/>		Calculated Result	<input type="checkbox"/>
LIS Code	<input type="text" value="OXY300"/>		Result Type	<input type="text" value="Qualitative"/>

UNITS AND RANGE SETTINGS

Use Settings from	<input type="text" value="None"/>	Units	<input type="text" value="None"/>	Decimal Places	<input type="text" value="x"/>	<input type="text" value="Urine"/>
Test Kind	<input type="text" value="General"/>	Revision	<input type="text" value="01"/>	<input checked="" type="checkbox"/> Multi Reagent Switch		
Reagent Name	<input type="text" value="OXY"/>	Reagent ID	<input type="text" value="557"/>	<input type="checkbox"/> FSE Test		
ABB Name	<input type="text" value="OXY2G"/>	Parameter Long Name	<input type="text" value="Oxycodone 300 (Q) 100248 OXY2G Urine"/>			
Region	<input checked="" type="checkbox"/> US <input checked="" type="checkbox"/> OUS <input checked="" type="checkbox"/> AP <input type="checkbox"/> JP <input checked="" type="checkbox"/> EU <input type="checkbox"/> Other					

GENERAL PARAMETERS

SAMPLE VOLUME	Sample Volume <input type="text" value="10.5"/> μ L	Dilution <input type="text" value="0"/> μ L	REACTION OD LIMIT	Low <input type="text" value="-2.0000"/>	High <input type="text" value="3.0000"/>
	Predilution Rate <input type="text" value="1"/>		REACTION BLANK OD LIMIT	First: Low <input type="text" value="-2.0000"/>	High <input type="text" value="3.0000"/>
REAGENT VOLUME	R1-1 <input type="text" value="87"/> μ L	Dilution <input type="text" value="0"/> μ L		Last: Low <input type="text" value="-2.0000"/>	High <input type="text" value="3.0000"/>
	R2-1 <input type="text" value="87"/> μ L	Dilution <input type="text" value="0"/> μ L	ANALYTICAL MEASURING RANGE	Low <input type="text" value="0.00"/>	High <input type="text" value="1000.00"/>
WAVELENGTH	Primary <input type="text" value="340"/> nm	Secondary <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"/>		REAGENT ONBOARD STABILITY	<input type="text" value="31"/> Days	<input type="text" value="0"/> Hours
REACTION SLOPE	<input type="text" value="+"/>		LIH INFLUENCE CHECK	<input type="checkbox"/> Perform LIH check	
MEASURING POINT	Point 1: First <input type="text" value="17"/>	Last <input type="text" value="21"/>	Lipemia	<input type="text" value="+"/>	
	Point 2: First <input type="text"/>	Last <input type="text"/>	Icterus	<input type="text" value="+"/>	
Linearity Limit	<input type="text"/> %		Hemolysis	<input type="text" value="+"/>	
Lag Time Check	<input type="checkbox"/> Perform Lag Time Check				

CALIBRATION PARAMETERS

Base Unit	Decimal Place	Unit 1	Factor 1	Unit 2	Factor 2	Unit 3	Factor 3	Unit 4	Factor 4
None ▼	0 ▼	None ▼	0	None ▼	0	None ▼	0	None ▼	0

CALIBRATOR SPECIFIC

Calibration Type

Counts

Use highest calibrator for Upper AMR

Formula

MB Factor

Calibrator Name Add

Positive Cutoff

SLOPE CHECK

Number of Levels

Slope Check

CALIBRATION OD AND CONCENTRATION PARAMETERS

	Calibrator Name	Conc	Factor Range Low	Factor Range High
Point 1	OXY CAL-3	300	-999999	99999
Point 2				
Point 3				
Point 4				
Point 5				
Point 6				
Point 7				

STABILITY AND INTERVAL

Reagent Blank Stability Days Hours
 Calibration Stability Days Hours

Interval

OD DELTA CHECK

Reagent Blank
 Calibration

PROZONE CHECK PARAMETERS

Logic Check 1

Check Points
 Point 1
 Point 2
 Point 3

Decision Values
 Value 1
 Value 2
 Value 3

Logic Check 2

Check Points
 Point 1
 Interval

Limit Points
 Limit 1
 Limit 2

Logic Check 3

Check Points
 Point 1
 Interval

Limit Points
 Limit 1
 Limit 2

Decision Values
 Value 1
 Value 2

Check Pattern
 Pattern

Reagent Name: DRI Oxycodone Assay (Semi-Quantitative- 100 ng/mL Cutoff Only) REF 100248 DxC 500 AU Urine Settings
Calibrator Name DRI Oxycodone Calibrators REF 1664, 100250, 100251, 100252, 100253

Reagent ID 557

TEST CONFIGURATION & CHEMISTRY DETAILS

Assay Name	Test	Rev	Discipline	Chemistry
Test ID	OXY100-		Calculated Result	<input type="checkbox"/>
LIS Code	OXY100-		Result Type	Semiquantitative ▼
UNITS AND RANGE SETTINGS				
Use Settings from	None ▼	Units	ng/mL ▼	Decimal Places
				x.xx ▼
Test Kind	General ▼	Revision	01	<input checked="" type="checkbox"/> Multi Reagent Switch
Reagent Name	OXY	Reagent ID	557	<input type="checkbox"/> FSE Test
ABB Name	OXY3G	Parameter Long Name	Oxycodone 100 S/Q 100248 OXY3G Urine	
Region	<input checked="" type="checkbox"/> US	<input checked="" type="checkbox"/> OUS	<input checked="" type="checkbox"/> AP	<input type="checkbox"/> JP
			<input checked="" type="checkbox"/> EU	<input type="checkbox"/> Other

GENERAL PARAMETERS

SAMPLE VOLUME	Sample Volume	10.5	µL	Dilution	0	µL	REACTION OD LIMIT	Low	-2.0000	High	3.0000	
	Predilution Rate	1	▼				REACTION BLANK OD LIMIT	First: Low	-2.0000	High	3.0000	
REAGENT VOLUME	R1-1	87	µL	Dilution	0	µL		Last: Low	-2.0000	High	3.0000	
	R2-1	87	µL	Dilution	0	µL	ANALYTICAL MEASURING RANGE	Low	0.00	High	1000.00	
WAVELENGTH	Primary	340	nm	Secondary	410	nm	MANUFACTURER FACTOR	A	1	B	0	
METHOD	FIXED 1 ▼						REAGENT ONBOARD STABILITY		31	Days	0	Hours
REACTION SLOPE	+						LIH INFLUENCE CHECK	<input type="checkbox"/> Perform LIH check				
MEASURING POINT	Point 1: First	17		Last	21		Lipemia	+ ▼				
	Point 2: First			Last			Icterus	+ ▼				
Linearity Limit			%				Hemolysis	+ ▼				
Lag Time Check				<input type="checkbox"/> Perform Lag Time Check								

Reagent Name: DRI Oxycodone Assay (Semi-Quantitative- 100 ng/mL Cutoff Only) REF 100248 DxC 500 AU Urine Settings
Calibrator Name DRI Oxycodone Calibrators REF 1664, 100250, 100251, 100252, 100253, Continued

Reagent ID 557

CALIBRATION PARAMETERS

Base Unit	Decimal Place	Unit 1	Factor 1	Unit 2	Factor 2	Unit 3	Factor 3	Unit 4	Factor 4
ng/mL	2	None	0	None	0	None	0	None	0

CALIBRATOR SPECIFIC

Calibration Type

Counts

Formula

MB Factor

Calibrator Name

Positive Cutoff

SLOPE CHECK Number of Levels

Slope Check

STABILITY AND INTERVAL

Reagent Blank Stability Days Hours

Interval

Calibration Stability Days Hours

Interval

CALIBRATION OD AND CONCENTRATION PARAMETERS

Use highest calibrator for Upper AMR

	Calibrator Name	Conc	OD Range Low	OD Range High
Point 1	OXY CAL-1	0.00	-2.00	3.00
Point 2	OXY CAL-2	100.00	-2.00	3.00
Point 3	OXY CAL-3	300.00	-2.00	3.00
Point 4	OXY CAL-4	500.00	-2.00	3.00
Point 5	OXY CAL-5	1000.00	-2.00	3.00
Point 6				
Point 7				

OD DELTA CHECK

Reagent Blank
 Calibration

PROZONE CHECK PARAMETERS

Logic Check 1

Check Points
 Point 1
 Point 2
 Point 3

Decision Values
 Value 1
 Value 2
 Value 3

Logic Check 2

Check Points
 Point 1
 Interval

Limit Points
 Limit 1
 Limit 2

Logic Check 3

Check Points
 Point 1
 Interval

Limit Points
 Limit 1
 Limit 2

Decision Values
 Value 1
 Value 2

Check Pattern
 Pattern

Reagent Name: DRI Oxycodone Assay (Semi-Quantitative- 300 ng/mL Cutoff Only) REF 100248 DxC 500 AU Urine Settings
Calibrator Name: DRI Oxycodone Calibrators REF 1664, 100250, 100251, 100252, 100253

Reagent ID 557

TEST CONFIGURATION & CHEMISTRY DETAILS

Assay Name	Test	Rev	Discipline	Chemistry
Test ID	OXY300-		Calculated Result	<input type="checkbox"/>
LIS Code	OXY300-		Result Type	Semiquantitative ▼
UNITS AND RANGE SETTINGS				
Use Settings from	None ▼	Units	ng/mL ▼	Decimal Places
				x.xx ▼
Test Kind	General ▼	Revision	01	<input checked="" type="checkbox"/> Multi Reagent Switch
Reagent Name	OXY	Reagent ID	557	<input type="checkbox"/> FSE Test
ABB Name	OXY4G	Parameter Long Name	Oxycodone 300 S/Q 100248 OXY4G Urine	
Region	<input checked="" type="checkbox"/> US	<input checked="" type="checkbox"/> OUS	<input checked="" type="checkbox"/> AP	<input type="checkbox"/> JP
			<input checked="" type="checkbox"/> EU	<input type="checkbox"/> Other

GENERAL PARAMETERS

SAMPLE VOLUME	Sample Volume	10.5	µL	Dilution	0	µL	REACTION OD LIMIT	Low	-2.0000	High	3.0000	
	Predilution Rate	1					REACTION BLANK OD LIMIT	First: Low	-2.0000	High	3.0000	
REAGENT VOLUME	R1-1	87	µL	Dilution	0	µL		Last: Low	-2.0000	High	3.0000	
	R2-1	87	µL	Dilution	0	µL	ANALYTICAL MEASURING RANGE	Low	0.00	High	1000.00	
WAVELENGTH	Primary	340	nm	Secondary	410	nm	MANUFACTURER FACTOR	A	1	B	0	
METHOD	FIXED 1 ▼						REAGENT ONBOARD STABILITY		31	Days	0	Hours
REACTION SLOPE	+						LIH INFLUENCE CHECK	<input type="checkbox"/> Perform LIH check				
MEASURING POINT	Point 1: First	17		Last	21		Lipemia	+ ▼				
	Point 2: First			Last			Icterus	+ ▼				
Linearity Limit			%				Hemolysis	+ ▼				
Lag Time Check				<input type="checkbox"/> Perform Lag Time Check								

Reagent Name: DRI Oxycodone Assay (Semi-Quantitative- 300 ng/mL Cutoff Only) REF 100248 DxC 500 AU Urine Settings

Reagent ID 557

Calibrator Name: DRI Oxycodone Calibrators REF 1664, 100250, 100251, 100252, 100253, Continued

CALIBRATION PARAMETERS

Base Unit	Decimal Place	Unit 1	Factor 1	Unit 2	Factor 2	Unit 3	Factor 3	Unit 4	Factor 4
ng/mL	2	None	0	None	0	None	0	None	0

CALIBRATOR SPECIFIC

Calibration Type

Counts

Formula

MB Factor

Calibrator Name

Positive Cutoff

SLOPE CHECK

Number of Levels

Slope Check

STABILITY AND INTERVAL

Reagent Blank Stability Days Hours

Interval

Calibration Stability Days Hours

Interval

CALIBRATION OD AND CONCENTRATION PARAMETERS

Use highest calibrator for Upper AMR

	Calibrator Name	Conc	OD Range Low	OD Range High
Point 1	OXY CAL-1	0.00	-2.00	3.00
Point 2	OXY CAL-2	100.00	-2.00	3.00
Point 3	OXY CAL-3	300.00	-2.00	3.00
Point 4	OXY CAL-4	500.00	-2.00	3.00
Point 5	OXY CAL-5	1000.00	-2.00	3.00
Point 6				
Point 7				

OD DELTA CHECK

Reagent Blank
 Calibration

PROZONE CHECK PARAMETERS

Logic Check 1

Check Points
 Point 1
 Point 2
 Point 3

Decision Values
 Value 1
 Value 2
 Value 3

Logic Check 2

Check Points
 Point 1
 Interval

Limit Points
 Limit 1
 Limit 2

Logic Check 3

Check Points
 Point 1
 Interval

Limit Points
 Limit 1
 Limit 2

Decision Values
 Value 1
 Value 2

Check Pattern
 Pattern

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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