

DRI[®] OXYCODONE APPLICATION

BECKMAN COULTER DxC 500 AU / 500i



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.

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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:

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 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 / 500i Urine Settings Calibrator Name DRI Oxycodone Calibrator REF 100250

Reagent ID 557

TEST CONFIGURATION & CHEMISTRY DETAILS

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

GENERAL PARAMETERS

SAMPLE VOLUME	Sample Volume	14.0	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						REAGENT ONBOARD STABILITY		31	Days	0	Hours
REACTION SLOPE	+						LIH INFLUENCE CHECK	☐ Perform LIH check				
MEASURING POINT	Point 1: First	17		Last	21		Lipemia	+	▼			
	Point 2: First			Last			Icterus	+	▼			
							Hemolysis	+	▼			
Linearity Limit												
Lag Time Check	☐ Perform Lag Time Check											

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

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	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				

OD DELTA CHECK

☐ Reagent Blank

☐ Calibration

PROZONE CHECK PARAMETERS

☐ Logic Check 1

Check Points

Point 1	0
Point 2	0
Point 3	0

Decision Values

Value 1	0
Value 2	0
Value 3	0

☐ Logic Check 2

Check Points

Point 1	0
Interval	1

Decision Values

Value 1	0
Value 2	0

☐ Logic Check 3

Check Points

Point 1	0
Interval	1

Decision Values

Value 1	0
Value 2	0

Limit Points

Limit 1	0
Limit 2	27

Limit Points

Limit 1	0
Limit 2	27

Limit Points

Limit 1	0
Limit 2	27

Check Pattern

Pattern

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

Reagent ID 557

TEST CONFIGURATION & CHEMISTRY DETAILS

Assay Name	Test	Rev	Discipline	Chemistry
Test ID	OXY300		Calculated Result	☐
LIS Code	OXY300		Result Type	Qualitative ▼

UNITS AND RANGE SETTINGS

Use Settings from	None ▼	Units	None ▼	Decimal Places	x ▼	Urine
Test Kind	General ▼	Revision	01	☒ Multi Reagent Switch		
Reagent Name	OXY	Reagent ID	557	☐ FSE Test		
ABB Name	OXY2G	Parameter Long Name	Oxycodone 300 (Q) 100248 OXY2G Urine			

Region ☒US ☒OUS ☒AP ☐JP ☒EU ☐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								Last: Low	-2.0000	High	3.0000
	R1-1	87	µL	Dilution	0	µL	ANALYTICAL MEASURING RANGE	Low	0.00	High	1000.00
	R2-1	87	µL	Dilution	0	µL					
WAVELENGTH	Primary	340	nm	Secondary	410	nm	MANUFACTURER FACTOR	A	1	B	0
METHOD		FIXED	▼				REAGENT ONBOARD STABILITY		31	Days	0
REACTION SLOPE		+									
MEASURING POINT	Point 1: First	17		Last	21		LIH INFLUENCE CHECK	☐ Perform LIH check			
	Point 2: First			Last			Lipemia	+	▼		
							Icterus	+	▼		
							Hemolysis	+	▼		
Linearity Limit			%								
Lag Time Check				☐ Perform Lag Time Check							

Reagent Name: DRI Oxycodone Assay (Qualitative- 300 ng/mL Cutoff Only) REF 100248
DxC 500 AU / 500i Urine Settings Calibrator Name DRI Oxycodone Calibrator REF
100251, 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
None ▼	0 ▼	None ▼	0	None ▼	0	None ▼	0	None ▼	0

CALIBRATOR SPECIFIC

Calibration Type

Counts

Formula

MB Factor

Calibrator Name

Positive Cutoff

Add

Number of Levels

Slope Check

☐ 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	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				

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 (Semi-Quantitative- 100 ng/mL Cutoff Only) REF 100248 DxC 500 AU / 500i 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	☐		
LIS Code	OXY100-		Result Type	Semiquantitative ▼		
UNITS AND RANGE SETTINGS						
Use Settings from	None ▼	Units	ng/mL ▼	Decimal Places	x.xx ▼	Urine
Test Kind	General ▼	Revision	01	☒ Multi Reagent Switch		
Reagent Name	OXY	Reagent ID	557	☐ FSE Test		
ABB Name	OXY3G	Parameter Long Name	Oxycodone 100 S/Q 100248 OXY3G Urine			
Region	☒ US ☒ OUS ☒ AP ☐ JP ☒ EU ☐ 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	☐ Perform LIH check				
MEASURING POINT	Point 1: First	17		Last	21		Lipemia	+	▼			
	Point 2: First			Last			Icterus	+	▼			
							Hemolysis	+	▼			
Linearity Limit												
Lag Time Check	☐ Perform Lag Time Check											

Reagent Name: DRI Oxycodone Assay (Semi-Quantitative- 100 ng/mL Cutoff Only) REF 100248 DxC 500 AU / 500i 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 5AB

Counts 2

Formula POLYGONAL

MB Factor

Calibrator Name Add OXY

Positive Cutoff 100

☒ SLOPE CHECK

Number of Levels 5

Slope Check +

STABILITY AND INTERVAL

Reagent Blank Stability Days
Calibration Stability Days

Interval Bottle
Interval Bottle

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 0
Point 2 0
Point 3 0

Decision Values

Value 1 0
Value 2 0
Value 3 0

Limit Points

Limit 1 0
Limit 2 27

Check Pattern

Pattern Pattern 1

☐ Logic Check 2

Check Points

Point 1 0
Interval 1

Limit Points

Limit 1 0
Limit 2 27

☐ Logic Check 3

Check Points

Point 1 0
Interval 1

Limit Points

Limit 1 0
Limit 2 27

Decision Values

Value 1 0
Value 2 0

Reagent Name: DRI Oxycodone Assay (Semi-Quantitative- 300 ng/mL Cutoff Only) REF 100248 DxC 500 AU / 500i 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	☐		
LIS Code	OXY300-		Result Type	Semiquantitative ▼		
UNITS AND RANGE SETTINGS						
Use Settings from	None ▼	Units	ng/mL ▼	Decimal Places	x.xx ▼	Urine
Test Kind	General ▼	Revision	01	☒ Multi Reagent Switch		
Reagent Name	OXY	Reagent ID	557	☐ FSE Test		
ABB Name	OXY4G	Parameter Long Name	Oxycodone 300 S/Q 100248 OXY4G Urine			
Region	☒ US ☒ OUS ☒ AP ☐ JP ☒ EU ☐ 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	☐ Perform LIH check				
MEASURING POINT	Point 1: First	17		Last	21		Lipemia	+	▼			
	Point 2: First			Last			Icterus	+	▼			
							Hemolysis	+	▼			
Linearity Limit												
Lag Time Check	☐ Perform Lag Time Check											

Reagent Name: DRI Oxycodone Assay (Semi-Quantitative- 300 ng/mL Cutoff Only) REF 100248 DxC 500 AU / 500i 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 **5AB**

Counts **2**

Formula **POLYGONAL**

MB Factor

Calibrator Name

Positive Cutoff **300**

Add **OXY**

☒ SLOPE CHECK

Number of Levels **5**

Slope Check **+**

STABILITY AND INTERVAL

Reagent Blank Stability Days Hours

Interval **Bottle**

Calibration Stability Days Hours

Interval **Bottle**

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 **0**
Point 2 **0**
Point 3 **0**

Decision Values

Value 1 **0**
Value 2 **0**
Value 3 **0**

Limit Points

Limit 1 **0**
Limit 2 **27**

Check Pattern

Pattern **Pattern 1**

☐ Logic Check 2

Check Points

Point 1 **0**
Interval **1**

Limit Points

Limit 1 **0**
Limit 2 **27**

☐ Logic Check 3

Check Points

Point 1 **0**
Interval **1**

Limit Points

Limit 1 **0**
Limit 2 **27**

Decision Values

Value 1 **0**
Value 2 **0**

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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