

# ANWENDUNG FÜR DRI® OXYCODONE BECKMAN COULTER DxC 500 AU



Beckman Coulter-Reagenz REF 100248

Diese Anwendung ist für die qualitative und semiquantitative Bestimmung von Oxycodon in humanem Urin vorgesehen.



Nur zur In-vitro-Diagnostik  
Verschreibungspflichtig

## Verwendungszweck



Die Informationen in diesem Anwendungsblatt sind eine Ergänzung zur Packungsbeilage. Die Packungsbeilage enthält Informationen zu Verwendungszweck, Reagenzienlagerung, Aufbereitung des Reagenz, Probensammlung, Probenvorbereitung, Probenlagerung, Qualitätskontrolle sowie weitere Leistungsdaten.

## Bestellinformationen

Artikel	Größe	Beckman Coulter-Nachbestellnummer
DRI Oxycodone Assay	1 x 68 ml	100248
DRI Negativkalibrator	1 x 10 ml	1664
DRI Oxycodone 100 ng/ml Kalibrator	1 x 10 ml	100250
DRI Oxycodone 300 ng/ml Kalibrator	1 x 10 ml	100251
DRI Oxycodone 500 ng/ml Kalibrator	1 x 10 ml	100252
DRI Oxycodone 1000 ng/ml Kalibrator	1 x 10 ml	100253
DRI Oxycodone 100 ng/ml Kontrolle	1 x 10 ml	100254
DRI Oxycodone 300 ng/ml Kontrolle	1 x 10 ml	100255
AU Bottle	20 x 30 ml	63094

## Technische Unterstützung

Wenden Sie sich für technische Unterstützung an die Beckman Coulter-Vertretung in Ihrer Region.

*Fortsetzung auf der nächsten Seite*

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## Reagenzien- lagerung

Informationen zur Reagenzienlagerung sind in der Packungsbeilage zu finden.

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## Analyse- verfahren

Informationen zum Betrieb des Analysegeräts sind in dessen Gebrauchsanweisung zu finden. Ausführliche Informationen zur Reagenzienvorbereitung sind in der Packungsbeilage zu finden.

Das Reagenz vor dem Füllen in die AU-Fläschchen 15 Minuten bei Kühltemperatur (2 bis 8 °C) äquilibrieren lassen. Reagenz R1 und Reagenz R2 wie in der folgenden Tabelle gezeigt in die entsprechenden AU-Fläschchen geben:

	AU-Reagenzflasche	
DRI Oxycodone Assay-Kit	R1-Fach	R2-Fach
Antikörper-/Substratreagenz <b>R1</b>	1 Fläschchen (30 ml)	
Enzymkonjugatreagenz <b>R2</b>		1 Fläschchen (30 ml)

Achtung: Diese Reagenzien müssen auf festen Positionen programmiert werden. Die Thermo Reagenzflaschen nicht direkt im AU-Analysegerät verwenden.

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## Ergebnisse und Dateninterpretation

Die Ergebnisse werden in ng/ml ausgegeben.

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## Probenvorbereitung

Ausführliche Informationen zur Probenvorbereitung sind in der Packungsbeilage zu finden. Die Packungsbeilage ist auf der Website von Thermo Fisher Scientific zu finden:

[www.thermofisher.com](http://www.thermofisher.com)

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## Kalibrierung

Verwenden Sie DRI Oxycodon-Kalibratoren. Die Kalibratoren sind flüssig und gebrauchsfertig. Die Konzentration der Kalibratoren ist der Packungsbeilage zu entnehmen.

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**Name des Reagens DRI Oxycodone Assay (Qualitativ – 100 ng/ml nur Cutoff)**  
**REF 100248 DxC 500 AU Urine Settings Name des Kalibrators DRI Oxycodone**  
**Kalibrator REF 100250**

Reagenz-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"/>	<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="OXY1G"/>	Parameter Long Name	<input type="text" value="Oxycodone 100 (Q) 100248 OXY1G Urine"/>			

Region  US  OUS  AP  JP  EU  Other

**GENERAL PARAMETERS**

<b>SAMPLE VOLUME</b>	Sample Volume <input type="text" value="14.0"/> $\mu\text{L}$	Dilution <input type="text" value="0"/> $\mu\text{L}$	<b>REACTION OD LIMIT</b>	Low <input type="text" value="-2.0000"/>	High <input type="text" value="3.0000"/>
	Predilution Rate <input type="text" value="1"/>		<b>REACTION BLANK OD LIMIT</b>	First: Low <input type="text" value="-2.0000"/>	High <input type="text" value="3.0000"/>
<b>REAGENT VOLUME</b>	R1-1 <input type="text" value="87"/> $\mu\text{L}$	Dilution <input type="text" value="0"/> $\mu\text{L}$		Last: Low <input type="text" value="-2.0000"/>	High <input type="text" value="3.0000"/>
	R2-1 <input type="text" value="87"/> $\mu\text{L}$	Dilution <input type="text" value="0"/> $\mu\text{L}$	<b>ANALYTICAL MEASURING RANGE</b>	Low <input type="text" value="0.00"/>	High <input type="text" value="1000.00"/>
<b>WAVELENGTH</b>	Primary <input type="text" value="340"/> nm	Secondary <input type="text" value="410"/> nm	<b>MANUFACTURER FACTOR</b>	A <input type="text" value="1"/>	B <input type="text" value="0"/>
<b>METHOD</b>	<input type="text" value="FIXED"/>		<b>REAGENT ONBOARD STABILITY</b>	<input type="text" value="31"/> Days	<input type="text" value="0"/> Hours
<b>REACTION SLOPE</b>	<input type="text" value="+"/>		<b>LIH INFLUENCE CHECK</b>	<input type="checkbox"/> Perform LIH check	
<b>MEASURING POINT</b>	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				

**Name des Reagens DRI Oxycodone Assay (Qualitativ – 100 ng/ml nur Cutoff)  
 REF 100248 Dx C 500 AU Urine Settings Name des Kalibrators DRI Oxycodone  
 Kalibrator REF 100250, Fortsetzung**

Reagenz-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

Use highest calibrator for Upper AMR

Formula

MB Factor

Calibrator Name

Positive Cutoff

Add

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**

	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   
 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

**Name des Reagens DRI Oxycodone Assay (Qualitativ – 300 ng/ml nur Cutoff)**  
**REF 100248 DxC 500 AU Urine Settings Name des Kalibrators DRI Oxycodone**  
**Kalibrator REF 100251**

Reagenz-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  US  OUS  AP  JP  EU  Other

**GENERAL PARAMETERS**

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

STABILITY AND INTERVAL

Reagent Blank Stability  Days  Hours

Interval

Calibration Stability  Days  Hours

Interval

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				

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

Name des Reagens DRI Oxycodone Assay (Semiquantitativ – 100 ng/ml nur Cutoff)

Reagenz-ID 557

REF 100248 DxC 500 AU Urine Settings

Name des Kalibrators DRI Oxycodone Kalibratoren REF 1664, 100250, 100251, 100252, 100253

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									

Name des Reagens DRI Oxycodone Assay (Semiquantitativ – 100 ng/ml nur Cutoff)

Reagenz-ID 557

REF 100248 DxC 500 AU Urine Settings

Name des Kalibrators DRI Oxycodone Kalibratoren REF 1664, 100250, 100251, 100252, 100253 Fortsetzung

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



Name des Reagens DRI Oxycodone Assay (Semiquantitativ – 300 ng/ml nur Cutoff)

Reagenz-ID 557

REF 100248 DxC 500 AU Urine Settings

Name des Kalibrators: DRI Oxycodone Kalibratoren REF 1664, 100250, 100251, 100252, 100253

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
REACTION SLOPE		+								
MEASURING POINT		Point 1: First	17	Last	21	LIH INFLUENCE CHECK	<input type="checkbox"/> Perform LIH check			
		Point 2: First		Last		Lipemia	+ ▼			
Linearity Limit						Icterus	+ ▼			
Lag Time Check						Hemolysis	+ ▼			
		<input type="checkbox"/> Perform Lag Time Check								

Name des Reagens DRI Oxycodone Assay (Semiquantitativ – 300 ng/ml nur Cutoff)

Reagenz-ID 557

REF 100248 DxC 500 AU Urine Settings

Name des Kalibrators: DRI Oxycodone Kalibratoren REF 1664, 100250, 100251, 100252, 100253 Fortsetzung

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

CALIBRATION OD AND CONCENTRATION PARAMETERS

Use highest calibrator for Upper AMR

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

OD DELTA CHECK

Reagent Blank

Calibration

	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				

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

Check Pattern  
 Pattern

## Weitere Informationen

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**Wichtiger Hinweis**

Da Beckman Coulter weder das Reagenz herstellt noch Qualitätskontrollen oder andere Prüfungen mit einzelnen Chargen durchführt, schließt Beckman Coulter jegliche Haftung für Qualitätsminderungen der gewonnenen Daten aus, die durch die Leistung des Reagenz, Abweichungen zwischen den Reagenzienchargen oder Protokoll-änderungen des Herstellers entstehen.

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**Versandschaden**

Bitte benachrichtigen Sie umgehend das Technical Support Center von Beckman Coulter, wenn Sie dieses Produkt beschädigt erhalten haben.

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*Ende*