

APPLICAZIONE DI DRI[®] OXYCODONE BECKMAN COULTER DxC 500 AU



Reagente Beckman Coulter REF 100248

La presente applicazione è destinata alla determinazione qualitativa e semiquantitativa dell'ossicodone nelle urine umane.



Solo per uso diagnostico in vitro
Solo su prescrizione medica

Usò previsto



Le informazioni fornite nel presente foglio applicativo costituiscono un'integrazione al foglio illustrativo della confezione. Consultare il foglio illustrativo per informazioni sull'uso previsto, la conservazione e preparazione del reagente, il prelievo, la preparazione e la conservazione dei campioni, il controllo di qualità e ulteriori dati sulle prestazioni.

Informazioni per l'ordine

Articolo	Formato	Numero di riordine Beckman Coulter
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
Flacone in AU	20 x 30 mL	63094

Supporto tecnico

Per il supporto tecnico, contattare il rappresentante locale Beckman Coulter.

Continua alla pagina seguente

Conservazione dei reagenti

Per informazioni sulla conservazione dei reagenti, fare riferimento al foglietto illustrativo.

Funzionamento dell'analizzatore

Per informazioni sul funzionamento dell'analizzatore, fare riferimento ai manuali dell'operatore. Per informazioni sulla preparazione completa dei reagenti, fare riferimento al foglietto illustrativo.

Prima di versare in flaconi AU, lasciare equilibrare il reagente per 15 minuti a temperatura refrigerata (2-8 °C). Dispensare il reagente R1 e il reagente R2 in appositi flaconi AU come indicato nella tabella seguente:

	Flacone per reagente AU	
Kit DRI Oxycodone Assay	Scomparto R1	Scomparto R2
Reagente anticorpo/substrato R1	Un flacone (30 mL)	
Reagente enzima-coniugato R2		Un flacone (30 mL)

Avvertenza: questi reagenti devono essere programmati in posizioni fisse. Non utilizzare i flaconi di reagente Thermo direttamente sull'analizzatore AU.

Risultati e interpretazione dei dati

I risultati verranno stampati in ng/mL.

Preparazione dei campioni

Per informazioni sulla preparazione completa del campione, fare riferimento al foglietto illustrativo. L'inserito del prodotto è disponibile sul sito Web di Thermo Fisher Scientific:

www.thermofisher.com

Calibrazione

Utilizzare i calibratori per ossicodone DRI. I calibratori sono liquidi e pronti all'uso. Per la concentrazione di ciascun calibratore, fare riferimento al foglietto illustrativo.

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="+"/>				
		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

STABILITY AND INTERVAL

Reagent Blank Stability Days Hours
 Calibration Stability Days Hours

Interval

OD DELTA CHECK

Reagent Blank
 Calibration

	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				

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

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"/>
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"/>	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="+"/>				
		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

Positive Cutoff

Add

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

Interval

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

Nome reagente: DRI Oxycodone Assay (Semi-Quantitative- 100 ng/mL Cutoff Only)

ID reagente 557

REF 100248 Impostazioni DxC 500 AU Urine

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

Nome reagente: DRI Oxycodone Assay (Semi-Quantitative- 100 ng/mL Cutoff Only)

ID reagente 557

REF 100248 Impostazioni DxC 500 AU Urine

Nome calibratore DRI Oxycodone Calibrators REF 1664, 100250, 100251, 100252, 100253, *Continua*

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

Nome reagente: DRI Oxycodone Assay (Semi-Quantitative- 300 ng/mL Cutoff Only)

ID reagente 557

REF 100248 Impostazioni DxC 500 AU Urine

Nome calibratore: DRI Oxycodone Calibrators 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	+ ▼			
						Hemolysis	+ ▼			
Lag Time Check						<input type="checkbox"/> Perform Lag Time Check				

Nome reagente: DRI Oxycodone Assay (Semi-Quantitative- 300 ng/mL Cutoff Only)

ID reagente 557

REF 100248 Impostazioni DxC 500 AU Urine

Nome calibratore: DRI Oxycodone Calibrators REF 1664, 100250, 100251, 100252, 100253, *Continua*

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

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

CALIBRATION OD AND CONCENTRATION PARAMETERS

	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	<input type="text" value="0"/>
Point 2	<input type="text" value="0"/>
Point 3	<input type="text" value="0"/>

Decision Values

Value 1	<input type="text" value="0"/>
Value 2	<input type="text" value="0"/>
Value 3	<input type="text" value="0"/>

Logic Check 2

Check Points

Point 1	<input type="text" value="0"/>
Interval	<input type="text" value="1"/>

Limit Points

Limit 1	<input type="text" value="0"/>
Limit 2	<input type="text" value="27"/>

Logic Check 3

Check Points

Point 1	<input type="text" value="0"/>
Interval	<input type="text" value="1"/>

Limit Points

Limit 1	<input type="text" value="0"/>
Limit 2	<input type="text" value="27"/>

Check Pattern
Pattern

Informazioni supplementari

Importante

Poiché Beckman Coulter non produce il reagente né esegue controlli di qualità o altre analisi sui singoli lotti, Beckman Coulter non può essere responsabile della qualità dei dati ottenuti in base alle prestazioni del reagente, di eventuali variazioni tra i lotti di reagente o delle modifiche al protocollo da parte del produttore.

Danni dovuti al trasporto

Se il prodotto risulta danneggiato alla consegna, contattare il centro di supporto tecnico Beckman Coulter.

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Fine