

CEDIA® BUPRENORPHINE ASSAY APPLICATION
BECKMAN COULTER AU400®, AU480®, AU640®, AU680®, AU2700®,
AU5400®, AU5800®



Catalog No. 100190, 100240, 10015658

Intended for the Semiquantitative Determination of the presence of Buprenorphine 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. For package inserts, visit www.thermoscientific.com/diagnostics and enter the assay name in the *Search* field.

Ordering Information

For ordering information, visit www.thermoscientific.com/diagnostics and enter the assay name in the *Search* field. Not all intended uses and applications mentioned here are available in every country. Please contact your local sales representative or distributor for more information.

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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.

Dispense adequate amounts of Reagent 1 (EA reagent) and Reagent 2 (ED Reagent) into appropriate containers. **Ensure that reagents have equilibrated to temperature of analyzer reagent compartment before starting analysis.**

Note: Under Specific Test Parameters/General Tab, Linearity % should be left blank, as reflected in the following pages. **Do Not Enter 0.**

Calibration

Refer to the package insert for information on calibration.

AU400/480 Contamination Avoidance Parameters							
No.	PRECEDING TEST NAME	FOLLOWING TEST NAME	REAGENT PROBE CLEANER	WASH COUNT	CANCEL	SAME USE	
						MIXER	CUVETTE
1.	BUPSQ R1	∞UA1b 224 R1	Water	5	Yes	No	Yes
2.*	BUPSQ R1	∞UA1b 224 R2	Water	5	Yes	No	Yes

∞ Refers to reagent part numbers B38858/B46435

*Note: When selecting a preceding R1 and a following R1, R2 to R2 is also automatically selected. There is no facility for selecting a preceding R2 and a following R2 on the AU480 instrument.

AU680/AU5800 Contamination Avoidance Parameters							
No.	PRECEDING TEST NAME	FOLLOWING TEST NAME	REAGENT PROBE CLEANER	WASH COUNT	EFFECTIVE OF WATER CLEANING	SAME USE	
						MIXER	CUVETTE
1.	BUPSQ	∞UA1b 224	Water	5	Yes	No	Yes

∞ Refers to reagent part numbers B38858/B46435.

AU640/2700/5400 Contamination Avoidance Parameters							
No.	PRECEDING TEST NAME	FOLLOWING TEST NAME	REAGENT PROBE CLEANER	WASH COUNT	CANCEL	SAME USE	
						MIXER	CUVETTE
1.	BUPSQ	∞UA1b 224	Water	5	Yes	No	Yes

∞ Refers to reagent part numbers B38858/B46435

Contamination may also be avoided by placing the assays in separate cuvette rings from each other eg. Buprenorphine (Inner ring) and Urine Albumin (outer)

Results and Data Interpretation

Qualitative results will be flagged as "positive" or "negative," depending on the assay cutoff defined by the user in the Specific Test Parameters window. Semiquantitative results will be printed in ng/mL.

CEDIA Buprenorphine Assay – Semiquantitative Beckman Coulter System Parameters, AU400/AU640/AU2700/AU5400

Specific Test Parameters	
General	LIH ISE Range
Test Name:	BupSQ < > Type: Urine < Operation: Yes <
Sample:	Volume: 6.5 μL Dilution: 0 μL Pre-Dilution Rate: 1
Reagents:	R1 Volume: 87 μL Dilution: 0 μL Min OD Max OD R2 Volume: 87 μL Dilution: 0 μL L: -2.00 H: 2.50
Wavelength:	Pri: 570 < Sec: 660 < Reagent OD limit: First L: -2.00 First H: 2.50 Last L: -2.00 Last H: 2.50
Method:	RATE1* < Dynamic Range: L: 0 H: 75
Reaction slope:	+ <
Measuring Point 1:	First: 24 Last: 27 Correlation Factor: A: 1 B: 0
Measuring Point 2:	First: Last: On-board stability period: #
Linearity:	%
No Lag Time:	<

Specific Test Parameters	
General	LIH ISE Range
Test Name:	BupSQ < > Type: Urine <
Value/Flag:	VALUE < Level L: # Level H: #
Normal Ranges:	Age L Age H
	Sex Year Month Year Month L H
<input type="checkbox"/> 1.	# < # # # # # #
<input type="checkbox"/> 2.	# < # # # # # #
<input type="checkbox"/> 3.	# < # # # # # #
<input type="checkbox"/> 4.	# < # # # # # #
<input type="checkbox"/> 5.	# < # # # # # #
<input type="checkbox"/> 6.	# < # # # # # #
	7. None Selected
	8. Out of Range L H
Panic Value:	# # Unit: ng/mL Decimal places: #

Calibration Specific	
General	ISE
Test Name:	BupSQ < > Type: Urine <
Calibration Type:	5AB < Formula: POLYGONAL < Counts: 2 Process: CONC <
Point 1:	Cal. No. # OD CONC 0 Factor/OD-L -2.00 Factor/OD-H 2.50
Point 2:	# # 5 -2.00 2.50
Point 3:	# # 20 -2.00 2.50
Point 4:	# # 50 -2.00 2.50
Point 5:	# # 75 -2.00 2.50
Point 6:	# # # # # #
Point 7:	# # # # # #
1-Point Cal. Point:	# <input type="checkbox"/> With CONC-0 Slope Check + < Advanced Calibration: # <
MB Type Factor:	# Calibration Stability Period: #

User Defined
* Can be run as FIXED1

CEDIA Buprenorphine Assay – Semiquantitative Beckman Coulter System Parameters, AU480/AU680

Specific Test Parameters	
General	LIH ISE Range
Test Name:	BupSQ < > Type: Urine < > Operation: Yes < >
Sample:	Volume: 6.5 μL Dilution: 0 μL Pre-Dilution Rate: 1
Reagents:	R1 Volume: 87 μL Dilution: 0 μL Min OD: L -2.00 H 3.00 R2 Volume: 87 μL Dilution: 0 μL Reagent OD limit: First L -2.00 First H 3.00 Last L -2.00 Last H 3.00
Wavelength:	Pri: 570 < > Sec: 660 < > Dynamic Range: L 0 H 75
Method:	FIXED1* < > Correlation Factor: A 1 B 0
Reaction slope:	+ < > On-board stability period: 32
Measuring Point 1:	First: 24 Last: 27
Measuring Point 2:	First: Last:
Linearity:	%
No Lag Time:	< >

Specific Test Parameters	
General	LIH ISE Range
Test Name:	BupSQ < > Type: Urine < >
Value/Flag:	VALUE < > Level L: # Level H: #
Normal Ranges:	Age L Age H
	Sex Year Month Year Month L H
<input type="checkbox"/> 1.	# < > # # # # # # #
<input type="checkbox"/> 2.	# < > # # # # # # #
<input type="checkbox"/> 3.	# < > # # # # # # #
<input type="checkbox"/> 4.	# < > # # # # # # #
<input type="checkbox"/> 5.	# < > # # # # # # #
<input type="checkbox"/> 6.	# < > # # # # # # #
	7. None Selected # #
	8. Out of Range L H # #
Panic Value:	# # Unit: ng/mL Decimal places: #

Calibration Specific	
General	ISE
Test Name:	BupSQ < > Type: Urine < >
Calibration Type:	5AB < > Formula: POLYGONAL < > Counts: 2 Process: CONC < >
Point 1:	Cal. No. # OD CONC 0 Factor/OD-L -2.00 Factor/OD-H 3.00
Point 2:	Cal. No. # OD CONC 5 Factor/OD-L -2.00 Factor/OD-H 3.00
Point 3:	Cal. No. # OD CONC 20 Factor/OD-L -2.00 Factor/OD-H 3.00
Point 4:	Cal. No. # OD CONC 50 Factor/OD-L -2.00 Factor/OD-H 3.00
Point 5:	Cal. No. # OD CONC 75 Factor/OD-L -2.00 Factor/OD-H 3.00
Point 6:	Cal. No. # OD CONC Factor/OD-L Factor/OD-H
Point 7:	Cal. No. # OD CONC Factor/OD-L Factor/OD-H
1-Point Cal. Point:	< > <input type="checkbox"/> With CONC-0 Slope Check + < > Advanced Calibration: < >
MB Type Factor:	< > Calibration Stability Period: 9

* Can be run as RATE1
User Defined Values

CEDIA Buprenorphine Assay – Semiquantitative Beckman Coulter System Parameters, AU5800

Specific Test Parameters					
General	LIH	ISE	Range		
Test Name:	BupSQ	<	>		
Type:	Urine	Operation:	Yes		
Sample:	Volume	6.5	μL		
Dilution:	0	μL	Pre-Dilution Rate:	1	
Reagents:	R1 Volume	87	μL		
Dilution:	0	μL	Min OD	Max OD	
R2 Volume:	87	μL	Dilution:	0	
Reagent OD limit:	L	-2.00	H	3.00	
Wavelength:	Pri.	570	Sec.	660	
Method:	FIXED1*	First L	-2.00	First H	3.00
Reaction slope:	+	Last L	-2.00	Last H	3.00
Measuring Point 1:	First	24	Last	27	
Dynamic Range:	L	0	H	75	
Measuring Point 2:	First		Last		
Correlation Factor:	A	1	B	0	
Linearity:	%	On-board stability period:	32		
No Lag Time:					

Specific Test Parameters						
General	LIH	ISE	Range			
Test Name:	BupSQ	<	>			
Type:	Urine					
Value/Flag:	VALUE	Level L:	#			
Level H:	#					
Normal Ranges:	Age L	Age H				
Sex	Year	Month	Year	Month	L	H
<input type="checkbox"/> 1.	#	#	#	#	#	#
<input type="checkbox"/> 2.	#	#	#	#	#	#
<input type="checkbox"/> 3.	#	#	#	#	#	#
<input type="checkbox"/> 4.	#	#	#	#	#	#
<input type="checkbox"/> 5.	#	#	#	#	#	#
<input type="checkbox"/> 6.	#	#	#	#	#	#
<input type="checkbox"/> 7.	None Selected		#	#	#	#
<input type="checkbox"/> 8.	Out of Range		L	H	#	#
Panic Value:	#	#	Unit:	ng/mL	Decimal places:	#

Calibration Specific						
General	ISE					
Test Name:	BupSQ	<	>			
Type:	Urine					
Calibration Type:	5AB	Formula:	POLYGONAL			
Counts:	2	Process:	CONC			
Point 1:	Cal. No.	OD	CONC	Factor/OD-L	Factor/OD-H	
Point 2:	#		0	-2.00	3.00	
Point 3:	#		5	-2.00	3.00	
Point 4:	#		20	-2.00	3.00	
Point 5:	#		50	-2.00	3.00	
Point 6:			75	-2.00	3.00	
Point 7:						
1-Point Cal. Point:	<input type="checkbox"/>	With CONC-0	Slope Check	+	Advanced Calibration:	<input type="checkbox"/>
MB Type Factor:		Calibration Stability Period:	9			

* Can be run as RATE1
User Defined Values

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