

**CEDIA® HEROIN METABOLITE (6-AM) APPLICATION** CE  
**BECKMAN COULTER AU400® , AU480® , AU640® , AU680® ,**  
**AU2700® , AU5400® , AU5800®**

Catalog No. 100107, 100108, 100186, 10015213

The CEDIA Heroin Metabolite (6-Acetylmorphine, or 6-AM) Assay is a homogeneous enzyme immunoassay for the in vitro qualitative and semiquantitative determination of heroin metabolite (6-AM) in human urine on automated clinical chemistry analyzers.

For In Vitro Diagnostic Use 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**

Materials available from Microgenics, a part of Thermo Fisher Scientific

Item	Size	Thermo Fisher Scientific Catalog No.
CEDIA Heroin Metabolite (6-AM) Assay	3 x 17 mL Kit	100107
	65 mL Kit	100108
	495 mL Kit	100186
	3 x 17 mL Kit	10015213
CEDIA Negative Calibrator	5 mL	1557416
	15 mL	1661388
CEDIA Heroin Metabolite (6-AM) Cutoff Calibrator	5 mL	100031
CEDIA Heroin Metabolite (6-AM) High Calibrator	5 mL	100034
MGC Select DAU Control Set	2 levels, 3 x 5 mL ea.	100202

To place an order or for technical service contact:

In USA	In Europe
(800) 232-3342 Fax (510) 979-5420	Tel: +49 (0)851-88 6890 Fax: +49 (0)851-88 68910



**Microgenics Corporation, part of Thermo Fisher Scientific**  
46500 Kato Road, Fremont, CA 94538 USA  
U.S. Toll free: (800) 232-3342 / Tel: (510) 979-5000  
U.S. Toll free fax: (800) 527-8001 / Fax: (510) 979-5420

EC REP Thermo Fisher Scientific Oy, Ratastie 2, P.O. Box 100, 01621 Vantaa, Finland

*Continued on next page*

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**Reagent Storage**

Refer to the package insert for information on reagent storage.

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**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.**

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**Results and Data Interpretation**

Refer to package insert for information on results and data interpretation.

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# CEDIA Heroin Metabolite Assay – Qualitative

## Beckman Coulter System Parameters, AU400/AU640/AU2700/AU5400

Specific Test Parameters			
General	LIH	ISE	Range
Test Name:	6AMQ	<	>
Type:	Urine	Operation: Yes	
Sample:	Volume: 5.5 $\mu$ L	Dilution: 0 $\mu$ L	Pre-Dilution Rate: 1
Reagents:	R1 Volume: 87 $\mu$ L	Dilution: 0 $\mu$ L	Min OD
	R2 Volume: 87 $\mu$ L	Dilution: 0 $\mu$ L	Max OD
			L: -2.00 H: 2.50
Wavelength:	Pri: 570	Sec: 660	Reagent OD limit:
Method:	RATE*		First L: -2.00 First H: 2.50
Reaction slope:	+		Last L: -2.00 Last H: 2.50
Measuring Point 1:	First: 24	Last: 27	Dynamic Range:
Measuring Point 2:	First:	Last:	L: # H: #
Linearity:	%		Correlation Factor:
No Lag Time:	No		A: 1 B: 0
			On-board stability period: #

Specific Test Parameters			
General	LIH	ISE	Range
Test Name:	6AMQ	<	>
Type:	Urine		
Value/Flag:	#	Level L: #	Level H: #
Normal Ranges:	Age L	Age H	
	Sex	Year	Month
<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: # Decimal places: #

Calibration Specific			
General	ISE		
Test Name:	6AMQ	<	>
Type:	Urine		
Calibration Type:	AB	Formula:	Y=AX+B
		Counts:	2
		Process:	CONC
Point 1:	Cal. No. #	OD	CONC 100
Point 2:			
Point 3:			
Point 4:			
Point 5:			
Point 6:			
Point 7:			
1-Point Cal. Point:	<input type="checkbox"/>	With CONC-0	Slope Check +
MB Type Factor:		Advanced Calibration	
		Calibration Stability Period:	#

# User Defined  
 \*Can also be run as FIXED

# CEDIA Heroin Metabolite Assay – Semiquantitative Beckman Coulter System Parameters, AU400/AU640/AU2700/AU5400

Specific Test Parameters											
General	LIH	ISE	Range								
Test Name:		6AMSQ		< >		Type:	Urine		Operation:	Yes	
Sample:	Volume	5.5	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
Method:	RATE1*						Last L	-2.00	Last H		2.50
Reaction slope:	+						Dynamic Range:	L	0	H 20	
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:	No										

Specific Test Parameters											
General	LIH	ISE	Range								
Test Name:		6AMSQ		< >		Type:	Urine				
Value/Flag:	#		Level L:	#		Level H:	#				
Normal Ranges:											
	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:		6AMSQ		< >		Type:	Urine				
Calibration Type:	3AB		Formula:	POLYGONAL		Counts:	2		Process:	CONC	
Point 1:	Cal. No.	#	OD		CONC	0.0	Factor/OD-L	-2.00	Factor/OD-H		2.50
Point 2:	Cal. No.	#			10.0		-2.00	2.50			
Point 3:	Cal. No.	#			20.0		-2.00	2.50			
Point 4:	Cal. No.										
Point 5:	Cal. No.										
Point 6:	Cal. No.										
Point 7:	Cal. No.										
1-Point Cal. Point:	<input type="checkbox"/>	<input type="checkbox"/>	With CONC-0	Slope Check	+	▼	Advanced Calibration	#			
MB Type Factor:			Calibration Stability Period:		#						

Can also be run as FIXED1  
#User Defined

# CEDIA Heroin Metabolite Assay – Qualitative Beckman Coulter System Parameters, AU480/AU680

Specific Test Parameters										
General		LIH	ISE	Range						
Test Name:	6AMQ	<	>	Type:	Urine	Operation:	Yes			
Sample Volume	5.5	μL	Dilution	0	μL	OD Limit				
Pre-Dilution Rate	1			Min. OD	-2.00	Max.	3.00			
Reagents	R1(R1-	87	μL	Dilution	0	μL	Reagent OD			
							First Low	-2.00	High	3.00
							Last Low	-2.00	High	3.00
	R2 (R2-1)	87	μL	Dilution	0	μL	Dynamic Range	#	High	#
							Correlation Factor A	1	B	0
Wavelength:	Pri.	570	nm	Sec.	660	nm	Factor for Maker A	1	B	0
Method:	FIXED*									
Reaction slope:	+									
Measuring Point 1:	First	24	Last	27	LIH Influence Check	#				
Measuring Point 2:	First		Last		Lipemia					
Linearity:	%									
No Lag Time:	No									
							Icterus			
							Hemolysis			

Specific Test Parameters															
General		LIH	ISE	Range											
Test Name:	6AM	<	>	Type:	Urine										
Value/Flag	#	Level L:	#	Level H:	†										
Specific Ranges:															
	Sex	Year	Mont	Year	Mont	Low	High								
<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. No demographics						#	#								
8. Not within expected						#	#								
Unit	#		Decimal Places	#											
<table border="1" style="float: right; margin-top: 10px;"> <tr> <th colspan="2">Panic</th> </tr> <tr> <td>Low</td> <td>High</td> </tr> <tr> <td>#</td> <td>#</td> </tr> </table>										Panic		Low	High	#	#
Panic															
Low	High														
#	#														

# User defined.

\* Can also be run as RATE

# CEDIA Heroin Metabolite Assay – Qualitative Beckman Coulter System Parameters, AU480/AU680, *continued*

Calibration Specific										
General		ISE								
Test Name:		6AM		<		>		Type	Urine	<input type="checkbox"/> Use Serum Cal.
Calibration Type:		AB		Formula		Y=AX+B		Counts:	2	
<Calibrator										
	Calibrator	OD	Conc	Factor Range				Slope Check	None	
				Low	High			Allowable Range Check		
Point 1:	#		100	-99999	999999			<input type="checkbox"/> Reagent		
Point								<input type="checkbox"/> Blank		
Point								<input type="checkbox"/> Calibration		
Point 3:								Advanced		
Point								Calibration		
Point 5:								Operation		
Point								No		
Point								Interval		
Point								(RB/ACAL)		
Point										
Point										
Point										
Point1										
<Point Cal. For Master		No. of Correction		Use Master				<input type="checkbox"/> Lot Calibration		
Calibrator		OD	Conc	OD Range				Stability		
				Low	High			Reagent Blanks		
Point								# Da		
Point								7 Da 0 Hour		
MB Type Factor:		1-Point Calibration Point						<input type="checkbox"/> With CONC-0		

# User defined.

# CEDIA Heroin Metabolite Assay – Semiquantitative Beckman Coulter System Parameters, AU480/AU680

Specific Test Parameters									
General		LIH	ISE	Range					
Test Name:	6AMSQ	<	>	Type:	Urine	Operation:	Yes		
Sample Volume	5.5	μL	Dilution	0	μL	OD Limit			
Pre-Dilution Rate	1			Min. OD	-	Max.	3.000		
Reagents	R1(R1-	87	μL	Dilution	0	μL	Reagent OD		
							First Low	-	High 3.000
							Last Low	-	High 3.000
	R2 (R2-1)	87	μL	Dilution	0	μL	Dynamic Range	0	High 20
							Correlation Factor A	1	B 0
Wavelength:	Pri.	570	nm	Sec.	660	nm	Factor for Maker A	1	B 0
Method:	FIXED1								
Reaction slope:	+								
Measuring Point 1:	First	24	Last	27	LIH Influence Check	#			
Measuring Point 2:	First		Last		Lipemia				
Linearity:	%								
No Lag Time:									
							Icterus		
							Hemolysis		

Specific Test Parameters									
General		ISE	Range						
Test Name:	6AMSQ	<	>	Type:	Urine				
Value/Flag	#	Level L:	#	Level H:	#				
Specific Ranges:									
	Sex	Year	Mont	Year	Mont	Low	High	Panic	
<input type="checkbox"/>	#	#	#	#	#	#	#	Low	High
<input type="checkbox"/>	#	#	#	#	#	#	#	#	#
<input type="checkbox"/>	#	#	#	#	#	#	#	#	#
<input type="checkbox"/>	#	#	#	#	#	#	#	#	#
<input type="checkbox"/>	#	#	#	#	#	#	#	#	#
<input type="checkbox"/>	#	#	#	#	#	#	#	#	#
<input type="checkbox"/>	7. No demographics					#	#		
<input type="checkbox"/>	8. Not within expected					#	#		
Unit	ng/mL		Decimal Places	#					

# User defined  
\* Can also be run as RATE1

# CEDIA Heroin Metabolite Assay – Semiquantitative Beckman Coulter System Parameters, AU480/AU680, *continued*

Calibration Specific									
General ISE									
Test Name:		6AMSQ		<	>	Type	Urine		<input type="checkbox"/> Use Serum Cal.
Calibration		3AB		Formul		POLYGONAL		Counts: 2	
<Calibrator									
	Calibrator	OD	Conc	Factor Range		Slope Check		+	
	#		0.0	Low	High	Allowable Range			
Point	#		10.0	-2.0000	3.0000	<input type="checkbox"/> Reagent			
Point	#		20.0	-2.0000	3.0000	<input type="checkbox"/> Calibration			
Point						Advanced			
Point						Operation		No	
Point						Interval			
Point									
Point									
Point									
Point									
Point1									
<Point Cal. For Master									
	Calibrator	No. of Correction	Conc	OD Range		Stability			
		OD		Low	High	Reagent Blanks		# Da # Hou	
Point						Calibration		7 Da 0 Hou	
Point									
MB Type Factor: 1-Point Calibration Point <input type="checkbox"/> With CONC-0									

# User Defined



# CEDIA Heroin Metabolite Assay – Qualitative Beckman Coulter System Parameters, AU5800

Parameters		Specific Test Parameters									
General	LIH	ISE	HbA1c		Calculated Test	Range					
Test Name:		6AMQ	<	>	Type:	Urine	Operation	Yes			
Sample Volume	5.5	μL	Dilution	0	μL	OD Limit					
Pre-Dilution Rate	1	▽	Diluent Bottle	Outside	▽	Min.OD	-2.00	Max.OD	3.00		
Rgt. Volume	R1(R1-1)	87	μL	Dilution	0	μL	Reagent OD Limit				
	R1-2		μL	Dilution		μL	1 <sup>st</sup> .	Low	-2.00	High	3.00
							Last	Low	-2.00	High	3.00
	R2(R2-1)	87	μL	Dilution	0	μL					
Common Rgt. Type	None		Name	None		Dynamic Range Low	#	High	#		
Wavelength	Pri	570	▽nm	Sec.	660	▽nm	Correlation Factor A	1	B	0	
Method	FIXED*					Factor for Maker	A	1	B	0	
Reaction Slope	+					Onboard Stability Period	30	Day	0	Hour	
Measuring Point1	1 <sup>st</sup>	24		Last	27	LIH Influence Check	#	▽			
Measuring Point2	1 <sup>st</sup>			Last		Lipemia		▽			
Linearity Limit			%			Icterus		▽			
Lag Time Check	No		▽			Hemolysis		▽			

Parameters		Specific Test Parameters						
General	LIH	ISE	HbA1c		Calculated Test	Range		
Test Name:		6AMQ	<	>	Type:	Urine		
Value/Flag:		#						
Level			Low	#	High	#		
Specific Ranges:		From	To		Low	High		
	Sex	Year	Month	Year	Month	Low	High	
<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.	Standard demographics				#	#	
	8.	Not within expected values				#	#	
Panic Value	Low	#	High	#	Unit	#	Decimal Places	#

# User defined.

\* Can also be run as RATE

# CEDIA Heroin Metabolite Assay – Qualitative Beckman Coulter System Parameters, AU5800, *continued*

Parameters	Calibration Parameters																																																																								
Calibrators	Calibration Specific	STAT Table Calibration																																																																							
Test Name: <input type="text" value="6AMQ"/> ▾	<input type="text" value="&lt;"/> <input type="text" value="&gt;"/>	Type <input type="text" value="Urine"/> ▾	Cuvette <input type="text" value=""/> ▾																																																																						
<input type="checkbox"/> Use Serum Cal																																																																									
<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td>Calibration Type: <input type="text" value="AB"/> ▾</td> <td>Formula: <input type="text" value="Y=AX+B"/> ▾</td> <td>Counts: <input type="text" value="2"/></td> </tr> <tr> <td colspan="3">&lt; Calibrator Parameters &gt;</td> </tr> <tr> <td style="text-align:center;">Calibrator</td> <td style="text-align:center;">OD</td> <td style="text-align:center;">Conc</td> <td style="text-align:center;">OD Range Low High</td> </tr> <tr> <td>Point-1</td> <td style="text-align:center;"># ▾</td> <td style="text-align:center;">100</td> <td style="text-align:center;">-99999 99999</td> </tr> <tr> <td>Point-2</td> <td style="text-align:center;">▾</td> <td></td> <td></td> </tr> <tr> <td>Point-3</td> <td style="text-align:center;">▾</td> <td></td> <td></td> </tr> <tr> <td>Point-4</td> <td style="text-align:center;">▾</td> <td></td> <td></td> </tr> <tr> <td>Point-5</td> <td style="text-align:center;">▾</td> <td></td> <td></td> </tr> <tr> <td>Point-6</td> <td style="text-align:center;">▾</td> <td></td> <td></td> </tr> <tr> <td>Point-7</td> <td style="text-align:center;">▾</td> <td></td> <td></td> </tr> <tr> <td>Point-8</td> <td style="text-align:center;">▾</td> <td></td> <td></td> </tr> <tr> <td>Point-9</td> <td style="text-align:center;">▾</td> <td></td> <td></td> </tr> <tr> <td>Point-10</td> <td style="text-align:center;">▾</td> <td></td> <td></td> </tr> <tr> <td colspan="2">&lt;Point Cal. For Master Curve&gt;</td> <td>No. of Correction Points <input type="text" value=""/> ▾</td> <td>Use Master Curve <input type="text" value=""/> ▾</td> </tr> <tr> <td style="text-align:center;">Calibrator</td> <td style="text-align:center;">OD</td> <td style="text-align:center;">Conc</td> <td style="text-align:center;">OD Range Low High</td> </tr> <tr> <td>Point-1</td> <td style="text-align:center;">▾</td> <td></td> <td></td> </tr> <tr> <td>Point-2</td> <td style="text-align:center;">▾</td> <td></td> <td></td> </tr> <tr> <td colspan="2">MB Type Factor <input type="text" value=""/></td> <td>1-Point Calibration Point <input type="text" value="None"/> ▾</td> <td><input type="checkbox"/> with Conc-0</td> </tr> </table>				Calibration Type: <input type="text" value="AB"/> ▾	Formula: <input type="text" value="Y=AX+B"/> ▾	Counts: <input type="text" value="2"/>	< Calibrator Parameters >			Calibrator	OD	Conc	OD Range Low High	Point-1	# ▾	100	-99999 99999	Point-2	▾			Point-3	▾			Point-4	▾			Point-5	▾			Point-6	▾			Point-7	▾			Point-8	▾			Point-9	▾			Point-10	▾			<Point Cal. For Master Curve>		No. of Correction Points <input type="text" value=""/> ▾	Use Master Curve <input type="text" value=""/> ▾	Calibrator	OD	Conc	OD Range Low High	Point-1	▾			Point-2	▾			MB Type Factor <input type="text" value=""/>		1-Point Calibration Point <input type="text" value="None"/> ▾	<input type="checkbox"/> with Conc-0
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<table style="width:100%;"> <tr> <td>Slope Check <input type="text" value="+"/> ▾</td> <td>Allowable Range Check</td> </tr> <tr> <td><input type="checkbox"/> Reagent Blank <input type="text" value=""/></td> <td><input type="checkbox"/> Calibration <input type="text" value=""/></td> </tr> <tr> <td colspan="2">Advanced Calibration</td> </tr> <tr> <td>Operation <input type="text" value="No"/> ▾</td> <td>Interval (RB/ACAL) <input type="text" value=""/> ▾</td> </tr> <tr> <td colspan="2"><input type="checkbox"/> Lot Calibration</td> </tr> <tr> <td>Stability</td> <td></td> </tr> <tr> <td>Reagent Blank <input type="text" value="#"/> Day <input type="text" value="#"/> Hour</td> <td></td> </tr> <tr> <td>Calibration <input type="text" value="14"/> Day <input type="text" value="0"/> Hour</td> <td></td> </tr> </table>				Slope Check <input type="text" value="+"/> ▾	Allowable Range Check	<input type="checkbox"/> Reagent Blank <input type="text" value=""/>	<input type="checkbox"/> Calibration <input type="text" value=""/>	Advanced Calibration		Operation <input type="text" value="No"/> ▾	Interval (RB/ACAL) <input type="text" value=""/> ▾	<input type="checkbox"/> Lot Calibration		Stability		Reagent Blank <input type="text" value="#"/> Day <input type="text" value="#"/> Hour		Calibration <input type="text" value="14"/> Day <input type="text" value="0"/> Hour																																																							
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# User defined

# CEDIA Heroin Metabolite Assay – Semiquantitative Beckman Coulter System Parameters, AU5800

Parameters		Specific Test Parameters									
General	LIH	ISE	HbA1c		Calculated Test	Range					
Test Name:		6AMSQ ▾	<	>	Type:	Urine ▾	Operation	Yes ▾			
Sample Volume	5.5	μL	Dilution	0	μL	OD Limit					
Pre-Dilution Rate	1	▽	Diluent Bottle	Outside	▽	Min.OD	-2.00	Max.OD	3.00		
Rgt. Volume	R1(R1-1)	87	μL	Dilution	0	μL	Reagent OD Limit				
	R1-2		μL	Dilution		μL	1 <sup>st</sup> .	Low	-2.00	High	3.00
							Last	Low	-2.00	High	3.00
	R2(R2-1)	87	μL	Dilution	0	μL					
Common Rgt. Type	None		Name	None		Dynamic Range Low	0	High	20		
Wavelength	Pri	570	▽nm	Sec.	660	▽nm	Correlation Factor A	1	B	0	
Method	FIXED1*					Factor for Maker A	1	B	0		
Reaction Slope	+					Onboard Stability Period	30	Day	0	Hour	
Measuring Point1 1 <sup>st</sup>	24		Last	27		LIH Influence Check	#	▽			
Measuring Point2 1 <sup>st</sup>			Last			Lipemia		▽			
Linearity Limit						Icterus		▽			
Lag Time Check	No					Hemolysis		▽			

Parameters		Specific Test Parameters									
General	LIH	ISE	HbA1c		Calculated Test	Range					
Test Name:		6AMSQ ▾	<	>	Type:	Urine ▾					
Value/Flag:		#		▽							
Specific Ranges:		From		Level To		Low	#	High	#		
	Sex	Year	Month	Year	Month	Low		High			
<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.	Standard demographics				#	#	#	#		
	8.	Not within expected values				#	#	#	#		
Panic Value	Low	#	High	#	Unit	ng/mL	Decimal Places	#			

\* Can be run as RATE1  
# User Defined Values

# CEDIA Heroin Metabolite Assay – Semiquantitative Beckman Coulter System Parameters, AU5800, *continued*

Parameters		Calibration Parameters	
Calibrators		Calibration Specific	STAT Table Calibration

Test Name:  < > Type  Cuvette 
  
 Use Serum Cal

Calibration Type:  Formula:  Counts:

< Calibrator Parameters >

	Calibrator	OD	Conc	OD Range	
				Low	High
Point-1	#		0.0	-2.0	3.0
Point-2	#		10.0	-2.0	3.0
Point-3	#		20.0	-2.0	3.0
Point-4					
Point-5					
Point-6					
Point-7					
Point-8					
Point-9					
Point-10					

Slope Check 
  
 Allowable Range Check
   
 Reagent Blank 
  
 Calibration 
  
 Advanced Calibration
   
 Operation 
  
 Interval (RB/ACAL) 
  
 Lot Calibration

<Point Cal. For Master Curve> No. of Correction Points  Use Master Curve

	Calibrator	OD	Conc.	OD Range	
				Low	High
Point-1					
Point-2					

Stability
   
 Reagent Blank  Day  Hour
   
 Calibration  Day  Hour

MB Type Factor  1-Point Calibration Point   with Conc-0

# User Defined Values

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## Precision

Samples of the Low Control, Cutoff Calibrator, and High Control were tested in replicates of 2, twice per day for 20 days, total N = 80/Level. The results are presented in the following tables:

Controls	Low Control	Cutoff Cal	High Control
<b>Qualitative AU480</b>			
Mean Rate (mA/min)	345	372	397
Within-Run SD (mA/min)	1.7	1.7	2.2
Within-Run CV (%)	0.5	0.4	0.5
Total SD (mA/min)	31.1	33.4	35.7
Total CV (%)	9.0	9.0	9.0
<b>Qualitative AU640</b>			
Mean Rate (mA/min)	345	373	400
Within-Run SD (mA/min)	2.4	2.4	2.3
Within-Run CV (%)	0.7	0.6	0.6
Total SD (mA/min)	4.3	5.4	5.2
Total CV (%)	1.2	1.4	1.3
<b>Qualitative AU680</b>			
Mean Rate (mA/min)	409	439	467
Within-Run SD (mA/min)	2.1	1.8	4.1
Within-Run CV (%)	0.5	0.4	0.9
Total SD (mA/min)	31.7	34.6	36.3
Total CV (%)	7.7	7.9	7.8
<b>Qualitative AU5800</b>			
Mean Rate (mA/min)	433	465	497
Within-Run SD (mA/min)	3.0	3.7	2.7
Within-Run CV (%)	0.7	0.8	0.6
Total SD (mA/min)	15.0	17.0	17.1
Total CV (%)	3.5	3.6	3.4

---

## Limit Of Blank

The negative calibrator was run against the same calibration curve for 21 replicates. The LOB is calculated as 3\*SD.

The observed LDD for Phencyclidine on:

AU480: 0.38 ng/mL

AU680: 0.62 ng/mL

AU5800: 0.51 ng/mL

**Precision,  
(Continued)**

<b>Controls</b>	<b>Low Control</b>	<b>Cutoff Cal</b>	<b>High Control</b>
<b>Semiquantitative AU480</b>			
Mean (ng/mL)	7.7	9.9	13.9
Within-Run SD (ng/mL)	0.20	0.28	0.31
Within-Run CV (%)	2.6	2.8	2.2
Total SD (ng/mL)	0.28	0.34	0.34
Total CV (%)	3.6	3.4	2.4
<b>Semiquantitative AU680</b>			
Mean (ng/mL)	7.9	10.1	14.0
Within-Run SD (ng/mL)	0.24	0.26	0.35
Within-Run CV (%)	3.0	2.6	2.5
Total SD (ng/mL)	0.32	0.37	0.41
Total CV (%)	4.1	3.7	2.9
<b>Semiquantitative AU5800</b>			
Mean (ng/mL)	7.8	9.9	14.0
Within-Run SD (ng/mL)	0.39	0.36	0.49
Within-Run CV (%)	5.0	3.6	3.5
Total SD (ng/mL)	0.48	0.55	0.64
Total CV (%)	6.1	5.6	4.6

**Accuracy and  
Correlation**

Patient samples were assayed using the CEDIA Heroin Metabolite (6-AM) Assay on the Beckman Coulter and tested against the reference analyzer, the Hitachi 717.

<b>Qualitative Method Comparison</b>			
	<b>Positive Agreement (%)</b>	<b>Negative Agreement (%)</b>	<b>Total Agreement (%)</b>
AU480	100.0%	95.8%	97.9%
AU640	100.0%	94.9%	97.8%
AU680	100.0%	95.8%	97.9%
AU5800	100.0%	98.4%	99.2%

**Accuracy and Correlation**  
(Continued)

**CEDIA Heroin Metabolite (6-AM) Assay Qualitative Method Comparison**

		Hitachi 717				Hitachi 717	
		+	-			+	-
AU480	+	48	3	AU640	+	52	2
	-	0	69		-	0	37
		Hitachi 717				Hitachi 717	
		+	-			+	-
AU680	+	48	3	AU5800	+	53	1
	-	0	69		-	0	61

Patient samples were assayed using the CEDIA Heroin Metabolite (6-AM) Assay on the Beckman Coulter and tested against the reference analyzer, the Hitachi 717.

Semi-Quantitative Method Comparison			
	Positive Agreement (%)	Negative Agreement (%)	Total Agreement (%)
AU480	96.4%	100.0%	98.0%
AU680	96.4%	100.0%	98.0%
AU5800	98.2%	100.0%	99.0%

**CEDIA Heroin Metabolite (6-AM) Assay Semi-Quantitative Method Comparison**

		Hitachi 717				Hitachi 717	
		+	-			+	-
AU480	+	53	0	AU680	+	53	0
	-	2	45		-	2	45
		Hitachi 717				Hitachi 717	
		+	-			+	-
AU680	+	54	0			+	0
	-	1	45			-	45

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