

**CEDIA® PROPOXYPHENE APPLICATION**



**Beckman Coulter AU400®, AU480®, AU640®, AU680®, AU2700®, AU5400®, AU5800®**

Catalog No. 100170, 100171, 1661523

Intended for the Qualitative and Semiquantitative Determination of Propoxyphene in Human Urine

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 Propoxyphene Assay Reagents	3x17 mL	100170
	65 mL	100171
	495 mL	1661523
CEDIA Negative Calibrator	5 mL	1557416
	15 mL	1661388
CEDIA PPX/Methadone Cutoff Calibrator	5 mL	1662848
CEDIA PPX/Methadone Intermediate Calibrator	5 mL	1662856
CEDIA PPX/Methadone High Calibrator	5 mL	1662864
MGC Primary DAU Control Set	3 x 5mL	100200

To place an order or for technical service contact:

USA	In Europe
(800) 232-3342 Fax 510-979-5002	Tel: +49 (0)851-88 6890 Fax: +49 (0)851-88 68910



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46500 Kato Road, Fremont, CA 94538 USA  
U.S. Toll free: (800) 232-3342 / Tel: (510) 979-5000  
U.S. Toll free fax: (888) 527-8001 / Fax: (510) 979-5420

**EC REP** Thermo Fisher Scientific Oy, Ratastie 2, P.O. Box 100, 01621 Vantaa, Finland  
Tel: +358-9-329100/Fax: +358-9-32910300

*Continued on next page*

## 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 EA Reagent (first reagent) and ED Reagent (second reagent) into appropriate containers place reagents onboard the analyzer prior starting analysis. **Ensure that the reagents have equilibrated to the temperature of the 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.**

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## Calibration

Refer to the package insert for information on calibration.

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## Results and Data Interpretation

When samples are assayed semi-quantitatively, results greater than or equal to the cutoff (300 ng/mL) are considered positive.

For further information, contact Microgenics Technical Support or your local Microgenics representative.

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**CEDIA PROPOXYPHENE Qualitative Assay**  
**Beckman Coulter System Parameters, AU400/AU640/AU2700/AU5400**

Specific Test Parameters	
General	LIH ISE Range
Test Name:	PPXQ ▾ < > Type: Urine ▾ Operation: Yes ▾
Sample:	Volume: 2.0 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:	RATE* ▾ Last L: -2.00 Last H: 2.50
Reaction slope:	+ ▾ Dynamic Range: L: # H: #
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:	PPXQ ▾ < > Type: Urine ▾
Value/Flag:	# ▾ 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: # Decimal places: #

Calibration Specific	
General	ISE
Test Name:	PPXQ ▾ < > Type: Urine ▾
Calibration Type:	AB ▾ Formula: Y=AX+B ▾ Counts: 2 Process: CONC ▾
Point 1:	Cal. No. # OD CONC -99999 Factor/OD-L 999999
Point 2:	
Point 3:	
Point 4:	
Point 5:	
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 also be run as FIXED

**CEDIA PROPOXYPHENE Semi-quantitative Assay**  
**Beckman Coulter System Parameters, AU400/AU640/AU2700/AU5400**

Specific Test Parameters			
General	LIH	ISE	Range
Test Name:	PPXSQ ▾	< >	Type: Urine ▾
Operation:	▾		
Sample:	Volume: 2.0 μL	Dilution: 0 μL	Pre-Dilution Rate: 1
Reagents:	R1 Volume: 87 μL	Dilution: 0 μL	Min OD
	R2 Volume: 87 μL	Dilution: 0 μL	Max OD
			L: -2.00 H: 3.00
Wavelength:	Pri: 570 ▾	Sec: 660 ▾	Reagent OD limit:
Method:	RATE1* ▾		First L: -2.00 First H: 3.00
			Last L: -2.00 Last H: 3.00
Reaction slope:	+ ▾		Dynamic Range:
Measuring Point 1:	First: 24	Last: 27	L: 0 H: 5000
Measuring Point 2:	First:	Last:	Correlation Factor:
Linearity:			A: 1 B: 0
No Lag Time:	No ▾		On-board stability period: #

Specific Test Parameters			
General	LIH	ISE	Range
Test Name:	PPXSQ ▾	< >	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.	# ▾	#	#
7.	None Selected		
8.	Out of Range		
		L	H
Panic Value:	#	#	Unit: ng/mL
			Decimal places: #

Calibration Specific			
General	ISE		
Test Name:	PPXSQ ▾	< >	Type: Urine ▾
Calibration Type:	4AB ▾	Formula: EIA TYPE 1 ▾	Counts: #
			Process: CONC ▾
Point 1:	Cal. No. #	OD	CONC 0
Point 2:	#		Factor/OD-L -2.00
Point 3:	#		Factor/OD-H 2.50
Point 4:	#		2.50
Point 5:			2.50
Point 6:			2.50
Point 7:			2.50
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 FIXED1

**CEDIA PROPOXYPHENE Qualitative Assay**  
**Beckman Coulter System Parameters, AU480 & AU680**

Specific Test Parameters											
General		LIH	ISE	Range							
Test Name:		PPXQ	<	>	Type:	Urine	Operation:		Yes		
Sample Volume	2.0	μL	Dilution	0	μL	OD Limit					
Pre-Dilution Rate	1				Min. OD	-2.00	Max. OD	3.00			
Reagents Volume:	R1(R1-1)	87	μL	Dilution	0	μL	Reagent OD limit:				
						First Low	-2.00	High	3.00		
						Last Low	-2.00	High	3.00		
		R2 (R2-1)	87	μL	Dilution	0	μL				
						Dynamic Range Low	#	High	#		
						Correlation Factor A	1	B	0		
						Factor for Maker A	1	B	0		
Wavelength:	Pri.	570	nm	Sec.	660	nm					
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										
						Onboard Stability		30	Days	0	Hour
						Icterus					
						Hemolysis					

Specific Test Parameters										
General		LIH	ISE	Range						
Test Name:		PPXQ	<	>	Type:	Urine				
Value/Flag:	#	Level L:	#	Level H:	#					
Specific Ranges:										
		From		To		Low	High			
<input type="checkbox"/>	1.	Sex	Year	Month	Year	Month	Low	High		
<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 values				#	#			
Unit	#	Decimal Places	#							
Panic Value										
		Low	#	High	#					

# User defined.  
 \* Can also be run as RATE

**CEDIA PROPOXYPHENE Qualitative Assay  
Beckman Coulter System Parameters, AU480 & AU680, Continued**

Calibration Specific										
General		ISE								
Test Name:		PPXQ	<	>	Type	Urine	<input type="checkbox"/> Use Serum Cal.			
Calibration Type:		AB	Formula:		Y=AX+B	Counts:	2			
<Calibrator Parameters>										
	Calibrator †	OD	Conc	Y	Factor Range		Slope Check			
					Low	High	None			
Point 1:	#		100		-99999	999999	Allowable Range Check			
Point 2:							<input type="checkbox"/> Reagent Blank			
Point 3:							<input type="checkbox"/> Calibration			
Point 4:							Advanced Calibration			
Point 5:							Operation			
Point 6:							Interval (RB/ACAL)			
Point 7:										
Point 8:										
Point 9:										
Point 10:										
<Point Cal. For Master Curve>		No. of Correction Points			Use Master Curve		<input type="checkbox"/> Lot Calibration			
	Calibrator	OD	Conc		OD Range		Stability			
					Low	High	Reagent Blanks Calibration			
Point 1:							#	Day	#	Hour
Point 2:							30	Day	0	Hour
MB Type Factor:			1-Point Calibration Point			<input type="checkbox"/> With CONC-0				

# User defined.

# CEDIA PROPOXYPHENE Semi-quantitative Assay Beckman Coulter System Parameters, AU480 & AU680

Specific Test Parameters									
General		LIH	ISE	Range					
Test Name:		PPXSQ	<	>	Type:	Urine	Operation:		Yes
Sample Volume	2.0	μL	Dilution	0	μL	OD Limit			
Pre-Dilution Rate	87			Min. OD	-2.00	Max. OD	3.00		
Reagents Volume:	R1(R1-1)	87	μL	Dilution	0	μL	Reagent OD limit:		
						First Low	-2.00	High	3.00
						Last Low	-2.00	High	3.00
	R2 (R2-1)	570	μL	Dilution	0	μL	Dynamic Range Low		0
							High	5000	
Wavelength:	Pri.	570	nm	Sec.	660	nm	Correlation Factor 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:			%		Icterus				
No Lag Time:	No				Hemolysis				

Specific Test Parameters										
General		ISE	Range							
Test Name:		PPXSQ	<	>	Type:	Urine				
Value/Flag:	#	Level L:	#	Level H:	#	Panic Value				
Specific Ranges:		From	To		Low	High				
<input type="checkbox"/>	1.	Sex	Year	Month	Year	Month	Low	High		
<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 values					#	#		
Unit	ng/mL		Decimal Places	#						

# User Define

\* Can also be run as RATE1

**CEDIA PROPOXYPHENE Semi-quantitative Assay**  
**Beckman Coulter System Parameters, AU480 & AU680 Continued**

Calibration Specific									
General		ISE							
Test Name:		PPXSQ ▾		<	>	Type:	Urine ▾		<input type="checkbox"/> Use Serum Cal.
Calibration Type:		4AB ▾		Formula:		POLYGONAL ▾		Counts: #	
<Calibrator Parameters>									
Calibrator ↑		OD	Conc	Factor Range		Slope Check		+ ▾	
				Low	High			Allowable Range Check	
Point 1:	# ▾		0	-2.00	3.00			<input type="checkbox"/> Reagent Blank	
Point 2:	# ▾		300	-2.00	3.00			<input type="checkbox"/> Calibration	
Point 3:	# ▾		1200	-2.00	3.00			Advanced Calibration	
Point 4:	# ▾		5000	-2.00	3.00			Operation ▾	
Point 5:	▾							Interval (RB/ACAL) ▾	
Point 6:	▾								
Point 7:	▾								
Point 8:	▾								
Point 9:	▾								
Point 10:	▾								
<Point Cal. For Master Curve>									
Calibrator		No. of Correction Points		Use Master Curve				<input type="checkbox"/> Lot Calibration	
		OD	Conc	OD Range		Stability			
				Low	High			Reagent Blanks	
Point 1:								30 Day 0 Hour	
Point 2:								Calibration	
MB Type Factor:			1-Point Calibration Point			<input type="checkbox"/> With CONC-0			

# User Define



**CEDIA PROPOXYPHENE Qualitative Assay**  
**Beckman Coulter System Parameters, AU5800**

Parameters		Specific Test Parameters			
General	LIH	ISE	HbA1c	Calculated Test	Range
Test Name: PPXQ < > Type: Urine Operation Yes					
Sample Volume	2.0 μL	Dilution	0 μL	OD Limit	
Pre-Dilution Rate	1	Diluent Bottle		Min.OD	-2.00 Max.OD 3.00
Rgt. Volume R1(R1-1)	87 μL	Dilution	0 μL	Reagent OD Limit	
R1-2		Dilution		1 <sup>st</sup> Low	-2.00 High 3.00
R2(R2-1)	87 μL	Dilution	0 μL	Last Low	-2.00 High 3.00
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	1 B 0
Reaction Slope	+			Onboard Stability Period	30 Day 0 Hour
Measuring Point 1 1 <sup>st</sup>	24	Last	27	LIH Influence Check	
Measuring Point 2 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: PPXQ < > Type: Urine					
Value/Flag:	#				
		Level	Low #	High #	
Specific Ranges:	From	To	Low	High	
	Sex	Year	Month	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.	#	#	#	#	#
7.	Standard demographics				#
8.	Not within expected values				#
Panic Value	Low	#	High	#	Unit # Decimal Places #

# User defined.  
 \* Can also be run as RATE

**CEDIA PROPOXYPHENE Qualitative Assay**  
**Beckman Coulter System Parameters, AU5800 Continued,**

Parameters		Calibration Parameters			
Calibrators		Calibration Specific			
General		ISE			
Test Name: PPXQ ▾		< > Type		Urine ▾	
		<input type="checkbox"/> Use Serum Cal.			
Calibration Type: AB ▾		Formula: Y=AX+B ▾		Counts: 2 ▾	
<Calibrator Parameters>					
		Range		Slope Check	
Calibrator		OD	Conc	Low	High
Point 1:	# ▾		100	-99999	999999
Point 2:	▾				
Point 3:	▾				
Point 4:	▾				
Point 5:	▾				
Point 6:	▾				
Point 7:	▾				
Point 8:	▾				
Point 9:	▾				
Point 10:	▾				
				Allowance Range Check	
				<input type="checkbox"/> Reagent Blank	
				<input type="checkbox"/> Calibration	
				Advanced Calibration	
				Operation	
				No ▾	
				Interval (RB/ACAL)	
				▾	
<Point Cal. For		No. of Correction Points		Use Master Curve	
Master Curve>		▾		▾ <input type="checkbox"/> Lot Calibration	
		OD Range		Stability	
Calibrator		OD	Conc	Low	High
Point-1	▾				
Point-2	▾				
MB Type Factor:		1-Point Calibration Point		None ▾ <input type="checkbox"/> with Conc-0	
				Reagent Blank # Day # Hour	
				Calibration 30 Day 0 Hour	

# User defined.

# CEDIA PROPOXYPHENE Semi-quantitative Assay Beckman Coulter System Parameters, AU5800

Parameters		Specific Test Parameters									
General	LIH	ISE	HbA1c		Calculated Test	Range					
Test Name:		PPXSQ	<	>	Type:	Urine	Operation	Yes			
Sample Volume	2.0	μL	Dilution	0	μL	OD Limit					
Pre-Dilution Rate	1	∇	Diluent Bottle	#	∇	Min.OD	-2.000	Max.OD	3.000		
Rgt. Volume	R1(R1-1)	87	μL	Dilution	0	μL	Reagent OD Limit				
	R1-2		μL	Dilution		μL	1 <sup>st</sup> .	Low	-2.000	High	3.000
							Last	Low	-2.000	High	3.000
	R2(R2-1)	87	μL	Dilution	0	μL					
Common Rgt. Type	None		Name	None		Dynamic Range Low	0	High	5000		
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						Hemolysis		∇			

Parameters		Specific Test Parameters							
General	LIH	ISE	HbA1c		Calculated Test	Range			
Test Name:			<	>	Type:	Urine			
Value/Flag:		PPXSQ							
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	#	

Parameters		Calibration Parameters						
Calibrators	Calibration Specific							
General	ISE							
Test Name:		PPXSQ	<	>	Type:	Urine	Cuvette .	
		<input type="checkbox"/> Use Serum Cal.						
Calibration Type:		4AB		Formula:	Polygonal		Counts:	#
<Calibrator Parameters>		Range						
Calibrator	OD	Conc	Low	High	Slope Check			
Point 1:	#	∇		0	-2.000	3.000	+	
Point 2:	#	∇		300	-2.000	3.000	Allowance Range Check	
Point 3:	#	∇		1200	-2.000	3.000	<input type="checkbox"/> Reagent Blank	
Point 4:	#	∇		5000	-2.000	3.000	<input type="checkbox"/> Calibration	
Point 5:		∇					Advanced Calibration	
Point 6:		∇					Operation	
Point 7:		∇					Interval (RB/ACAL)	
Point 8:		∇					∇	
Point 9:		∇						
Point 10:		∇						
<Point Cal. For	No. of Correction Points		∇	Use Master Curve		∇	<input type="checkbox"/> Lot Calibration	
Master Curve>		OD Range						
Calibrator	OD	Conc	Low	High	Stability			
Point-1					Reagent Blank	#	Day	#
Point-2					Calibration	30	Day	0
MB Type Factor:	1-Point Calibration Point				+			
					<input type="checkbox"/> with Conc-0			

# User defined.

\* Can also be run as RATE1

## Precision

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

	Control Low	Cutoff	Control High
<b>Qualitative AU400*</b>			
Mean (mA/min)	241	272	316
Within-Run SD (mA/min)	3.0	5.6	3.0
Within-Run CV (%)	1.3	1.6	1.0
Total SD (A/min)	5.0	8.9	6.2
Total CV (%)	2.1	3.3	2.0
<b>Qualitative AU480</b>			
Mean (mA/min)	223	259	288
Within-Run SD (mA/min)	3.3	2.0	2.0
Within-Run CV (%)	1.5	0.8	0.7
Total SD (A/min)	4.7	3.7	4.4
Total CV (%)	2.1	1.4	1.5
<b>Qualitative AU640*</b>			
Mean (mA/min)	214	252	288
Within-Run SD (mA/min)	2.0	2.4	3.0
Within-Run CV (%)	0.9	1.0	1.0
Total SD (A/min)	3.8	4.2	5.2
Total CV (%)	1.8	1.7	1.8
<b>Qualitative AU680</b>			
Mean (mA/min)	187	217	241
Within-Run SD (mA/min)	2.8	2.1	2.0
Within-Run CV (%)	1.5	1.0	0.8
Total SD (A/min)	3.8	4.5	3.9
Total CV (%)	2.0	2.1	1.6
<b>Qualitative AU5800</b>			
Mean (mA/min)	217	240	276
Within-Run SD (mA/min)	3.7	4.6	4.9
Within-Run CV (%)	1.7	1.9	1.8
Total SD (A/min)	7.1	7.1	9.3
Total CV (%)	3.3	3.0	3.4

\*N=60

**Precision  
(Continued)**

	Control Low	Cutoff	Control High
<b>Semiquantitative AU400*</b>			
Mean (ng/mL)	259	336	444
Within-Run SD (ng/mL)	7.6	15.1	12.2
Within-Run CV (%)	2.9	4.5	2.7
Total SD (ng/mL)	15.9	19.3	27.7
Total CV (%)	6.2	5.7	6.2
<b>Semiquantitative AU480</b>			
Mean (ng/mL)	232	305	449
Within-Run SD (ng/mL)	6.2	7.4	10.1
Within-Run CV (%)	2.7	2.4	2.2
Total SD (ng/mL)	8.9	13.6	16.6
Total CV (%)	3.8	4.4	3.7
<b>Semiquantitative AU640*</b>			
Mean (ng/mL)	236	329	428
Within-Run SD (ng/mL)	5.9	5.8	8.6
Within-Run CV (%)	2.5	1.8	2.0
Total SD (ng/mL)	10.1	10.7	15.9
Total CV (%)	4.3	3.2	3.7
<b>Semiquantitative AU680</b>			
Mean (ng/mL)	234	314	457
Within-Run SD (ng/mL)	6.2	9.3	12.0
Within-Run CV (%)	2.6	3.0	2.6
Total SD (ng/mL)	8.2	18.8	17.7
Total CV (%)	3.5	6.0	3.9
<b>Semiquantitative AU5800</b>			
Mean (ng/mL)	252	305	484
Within-Run SD (ng/mL)	5.8	14.5	24.5
Within-Run CV (%)	2.3	4.8	5.1
Total SD (ng/mL)	8.3	16.8	29.6
Total CV (%)	3.3	5.5	6.1

\*N=60

**Accuracy and  
Correlation**

Patient samples were assayed using the CEDIA Propoxyphene Assay on the Beckman Coulter and tested against the reference analyzer, the Hitachi 717.

<b>Qualitative Method Comparison</b>			
	Positive Agreement (%)	Negative Agreement (%)	Total Agreement (%)
AU400	100	100	100
AU480	100	100	100
AU640	100	100	100
AU680	100	100	100
AU5800	100	100	100

**Accuracy and Correlation**  
(Continued)

**CEDIA Propoxyphene Tox Assay Qualitative Method Comparison**

	Hitachi 717			Hitachi 717			Hitachi 717				
	+	-		+	-		+	-			
AU400	+	55	0	AU480	+	44	0	AU640	+	55	0
	-	0	77		-	0	56		-	0	70
	Hitachi 717			Hitachi 717							
	+	-		+	-						
AU680	+	44	0	AU5800	+	52	0				
	-	0	56		-	0	68				

**Semiquantitative Method Comparison**

	Positive Agreement (%)	Negative Agreement (%)	Total Agreement (%)
AU400	100	100	100
AU480	100	100	100
AU640	100	100	100
AU680	100	98.2	99.0
AU5800	100	100	100

**CEDIA Propoxyphene Assay Semiquantitative Method Comparison**

	Hitachi 717			Hitachi 717			Hitachi 717				
	+	-		+	-		+	-			
AU400	+	55	0	AU480	+	44	0	AU640	+	55	0
	-	0	77		-	0	56		-	0	77
	Hitachi 717			Hitachi 717							
	+	-		+	-						
AU680	+	44	1	AU5800	+	52	0				
	-	0	55		-	0	68				

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