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DRI® TRICYCLICS SERUM TOX APPLICATION Beckman Coulter AU400®, AU480®, AU640®, AU680®, AU2700®, AU5400®, AU5800®

CE

Catalog No. 1128

The DRI Tricyclics Serum Tox Assay is intended for the qualitative and semiquantitative determination of tricyclic antidepressants in human serum or plasma or 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 Number
DRI Tricyclics Serum Tox Kit	R1 25 mL R2 8 mL	1128
DRI Serum Tox Negative Calibrator	10 mL	0962
DRI Serum Tox Calibrator 1	5 mL	0963
DRI Serum Tox Calibrator 2	5 mL	0965
DRI Serum Tox Calibrator 3	5 mL	0967
DRI Serum Tox Calibrator 4	5 mL	0976
MAS TOX Control 1 – 3	6 x 5 mL	10011608

To place an order or for technical service, contact:

USA	In Europe
Tel: (800) 232-3342 **Fax: (510) 979-5420**	**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
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EC REP Microgenics GmbH, Spitalhofstrasse 94, 94032 Passau, Germany

Continued on next page

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.
Results and Data Interpretation	Results for samples will be printed in ng/mL.

Clinical Diagnostics
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DRI Tricyclics Serum Tox Qualitative Application
Beckman Coulter System Parameters, AU400/AU640/AU2700/AU5400

Specific Test Parameters

General | LIH | ISE | Range

Test Name: TCACQ ▽ < > Type: Serum ▽ Operation: Yes ▽

Sample:	Volume	8.0	µL	Dilution	0	µL	Pre-Dilution Rate:	1	
Reagents:	R1 Volume	180	µL	Dilution	0	µL	Min OD		Max OD
	R2 Volume	60	µL	Dilution	0	µL	L -2.00		H 2.50
							Reagent OD limit:		
Wavelength:	Pri.	340 ▽		Sec.	520 ▽		First L -2.00		First H 2.50
Method:		FIXED1* ▽					Last L -2.00		Last H 2.50
Reaction slope:		+ ▽					Dynamic Range:		
Measuring Point 1:	First	14		Last	20		L #		H #
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: TCACQ ▽ < > Type: Serum ▽

Value/Flag: # ▽ Level L: # Level H: †

Normal Ranges:

	Sex	Age L Year	Age L Month	Age H Year	Age H Month	L	H
☐ 1.	# ▽	#	#	#	#	#	#
☐ 2.	# ▽	#	#	#	#	#	#
☐ 3.	# ▽	#	#	#	#	#	#
☐ 4.	# ▽	#	#	#	#	#	#
☐ 5.	# ▽	#	#	#	#	#	#
☐ 6.	# ▽	#	#	#	#	#	#
7. None Selected						#	#
8. Out of Range		L		H		#	#

Panic Value: L # H # Unit: % Decimal places: #

Calibration Specific

General | ISE

Test Name: TCACQ ▽ < > Type Serum ▽

Calibration Type: AA ▽ Formula: Y=AX+B ▽ Counts: 2 Process: CONC ▽

	Cal. No.	OD	CONC	Factor/OD-L	Factor/OD-H
Point 1:	#		0	-99999	999999
Point 2:	#		100	-99999	999999
Point 3:					
Point 4:					
Point 5:					
Point 6:					
Point 7:					

1-Point Cal. Point: ☐ With CONC-0 Slope Check + ▽ Advanced Calibration: ▽

MB Type Factor: Calibration Stability Period: #

\# User defined

* Can also be run as RATE1

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DRI Tricyclics Serum Tox Semiquantitative Application
Beckman Coulter System Parameters, AU400/AU640/AU2700/AU5400

Specific Test Parameters

General | LIH | ISE | Range

Test Name: TCASQ ▽ < > Type: Serum ▽ Operation: Yes ▽

Sample:	Volume	8.0 µL	Dilution	0 µL	Pre-Dilution Rate:	1		
Reagents:	R1 Volume	180 µL	Dilution	0 µL	Min OD		Max OD	
	R2 Volume	60 µL	Dilution	0 µL	L	-2.00	H	2.50
					Reagent OD limit:			
Wavelength:	Pri.	340 ▽	Sec.	520 ▽	First L	-2.00	First H	2.50
Method:		FIXED1* ▽			Last L	-2.00	Last H	2.50
Reaction slope:		+ ▽			Dynamic Range:			
Measuring Point 1:	First	14	Last	20	L	0	H	1000
Measuring Point 2:	First		Last		Correlation Factor:			
Linearity:		%			A	1.0000	B	0.0000
No Lag Time:		No ▽			On-board stability period:	#		

Specific Test Parameters

General | LIH | ISE | Range

Test Name: TCASQ ▽ < > Type: Serum ▽

Value/Flag: # ▽ Level L: # Level H: #

Normal Ranges:

	Sex	Age L Year	Age L Month	Age H Year	Age H Month	L	H
☐ 1.	# ▽	#	#	#	#	#	#
☐ 2.	# ▽	#	#	#	#	#	#
☐ 3.	# ▽	#	#	#	#	#	#
☐ 4.	# ▽	#	#	#	#	#	#
☐ 5.	# ▽	#	#	#	#	#	#
☐ 6.	# ▽	#	#	#	#	#	#
7. None Selected						#	#
8. Out of Range		L		H		#	#

Panic Value: L # H # Unit: ng/mL Decimal places: #

Calibration Specific

General | ISE

Test Name: TCASQ ▽ < > Type Serum ▽

Calibration Type: 5AB ▽ Formula: EIA TYPE 1 ▽ Counts: 2 Process: CONC ▽

	Cal. No.	OD	CONC	Factor/OD-L	Factor/OD-H
Point 1:	#		0	-2.000	2.5000
Point 2:	#		150	-2.000	2.5000
Point 3:	#		300	-2.000	2.5000
Point 4:	#		500	-2.000	2.5000
Point 5:	#		1000	-2.000	2.5000
Point 6:					
Point 7:					

1-Point Cal. Point: ☐ With CONC-0 Slope Check + ▽ Advanced Calibration: ▽

MB Type Factor: Calibration Stability Period: #

* Can also be run as RATE1

\# User defined

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DRI Tricyclics Serum Tox Qualitative Application
Beckman Coulter System Parameters, AU480/AU680

Specific Test Parameters

General | LIH | ISE | Range

Test Name: TCACQ ▽ < > Type: Serum ▽ Operation: Yes ▽

Sample Volume		7.2 µL	Dilution	0 µL	OD Limit			
Pre-Dilution Rate		1				Min. OD	-2.00	Max. OD 3.00
Reagents Volume:	R1(R1-1)	162 µL	Dilution	0 µL	Reagent OD limit:			
						First Low	-2.00	High 3.00
						Last Low	-2.00	High 3.00
	R2 (R2-1)	54 µL	Dilution	0 µL				
						Dynamic Range Low	#	High #
						Correlation Factor A	1	B 0
Wavelength:	Pri.	340 nm	Sec.	520 nm		Factor for Maker A	1	B 0
Method:		FIXED1* ▽						
Reaction slope:		+ ▽				Onboard Stability	32 Days	0 Hour
Measuring Point 1:	First	14	Last	20		LIH Influence Check	# ▽	
Measuring Point 2:	First		Last			Lipemia	▽	
Linearity:		%				Icterus	▽	
No Lag Time:		No ▽				Hemolysis	▽	

Specific Test Parameters

General | | ISE | Range

Test Name: TCACQ ▽ < > Type: Serum ▽

Value/Flag: # ▽ Level L: # Level H: †

Specific Ranges:

		Sex	From Year	From Month	To Year	To Month	Low	High
☐	1.	# ▽	#	#	#	#	#	#
☐	2.	# ▽	#	#	#	#	#	#
☐	3.	# ▽	#	#	#	#	#	#
☐	4.	# ▽	#	#	#	#	#	#
☐	5.	# ▽	#	#	#	#	#	#
☐	6.	# ▽	#	#	#	#	#	#
	7. No demographics						#	#
	8. Not within expected values						#	#

Panic Value: Low # High #

Unit % Decimal Places #

Calibration Specific

General | ISE

Test Name: TCACQ ▽ < > Type Urine ▽ ☐ Use Serum Cal.

Calibration Type: AA ▽ Formula: Y=AX+B ▽ Counts: 2

<Calibrator Parameters> Slope Check + ▽

	Calibrator †	OD	Conc	Factor Range Low	Factor Range High
Point 1:	# ▽		0	-99999	999999
Point 2:	# ▽		100	-99999	999999
Point 3:	▽				
Point 4:	▽				
Point 5:	▽				
Point 6:	▽				
Point 7:	▽				
Point 8:	▽				
Point 9:	▽				
Point10:	▽				

Allowable Range Check: ☐ Reagent Blank ☐ Calibration

Advanced Calibration: Operation ▽ Interval (RB/ACAL) ▽

<Point Cal. For Master Curve> No. of Correction Points ▽ Use Master Curve ▽ ☐ Lot Calibration

	Calibrator	OD	Conc	OD Range Low	OD Range High
Point 1:					
Point 2:					

Stability: Reagent Blanks # Day # Hour; Calibration 18 Day 0 Hour

MB Type Factor: 1-Point Calibration Point ▽ ☐ With CONC-0

User defined.

* Can also be run as RATE1

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DRI Tricyclics Serum Tox Semiquantitative Application
Beckman Coulter System Parameters, AU480/AU680

Specific Test Parameters

General | LIH | ISE | Range

Test Name: TCASQ ▽ < > Type: Serum ▽ Operation: Yes ▽

Sample Volume		7.2 µL	Dilution	0 µL	OD Limit			
Pre-Dilution Rate		1				Min. OD	-2.000	Max. OD 3.00
Reagents Volume:	R1(R1-1)	162 µL	Dilution	0 µL	Reagent OD limit:			
						First Low	-2.000	High 3.000
						Last Low	-2.000	High 3.000
	R2 (R2-1)	54 µL	Dilution	0 µL				
						Dynamic Range Low	0	High 1000
						Correlation Factor A	1	B 0
Wavelength:	Pri.	340 nm	Sec.	520 nm		Factor for Maker A	1	B 0
Method:		FIXED1* ▽						
Reaction slope:		+ ▽				Onboard Stability	32 Days	0 Hour
Measuring Point 1:	First	14	Last	20		LIH Influence Check	# ▽	
Measuring Point 2:	First		Last			Lipemia	▽	
Linearity:		%				Icterus	▽	
No Lag Time:		No ▽				Hemolysis	▽	

Specific Test Parameters

General | | ISE | Range

Test Name: TCASQ ▽ < > Type: Serum ▽

Value/Flag: # ▽ Level L: # Level H: #

Specific Ranges:

	Sex	From Year	From Month	To Year	To Month	Low	High
☐ 1.	# ▽	#	#	#	#	#	#
☐ 2.	# ▽	#	#	#	#	#	#
☐ 3.	# ▽	#	#	#	#	#	#
☐ 4.	# ▽	#	#	#	#	#	#
☐ 5.	# ▽	#	#	#	#	#	#
☐ 6.	# ▽	#	#	#	#	#	#
7. No demographics						#	#
8. Not within expected values						#	#

Panic Value

Low	High
#	#

Unit ng/mL Decimal Places #

Calibration Specific

General | ISE

Test Name: TCASQ ▽ < > Type Serum ▽ ☐ Use Serum Cal.

Calibration Type: 5AB ▽ Formula: POLYGONAL ▽ Counts: 2

<Calibrator Parameters> Slope Check + ▽

Calibrator †		OD	Conc	Factor Range Low	Factor Range High
Point 1:	# ▽		0	-2.0000	3.0000
Point 2:	# ▽		150	-2.0000	3.0000
Point 3:	# ▽		300	-2.0000	3.0000
Point 4:	# ▽		500	-2.0000	3.0000
Point 5:	# ▽		1000	-2.0000	3.0000
Point 6:	▽				
Point 7:	▽				
Point 8:	▽				
Point 9:	▽				
Point10:	▽				

Allowable Range Check
☐ Reagent Blank
☐ Calibration

Advanced Calibration
Operation No ▽
Interval (RB/ACAL) ▽

<Point Cal. For Master Curve> No. of Correction Points ▽ Use Master Curve ▽ ☐ Lot Calibration

Calibrator	OD	Conc	OD Range Low	OD Range High
Point 1:				
Point 2:				

Stability
Reagent Blanks # Day # Hour
Calibration 18 Day 0 Hour

MB Type Factor: 1-Point Calibration Point ▽ ☐ With CONC-0

User Defined

* Can also be run as RATE1

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DRI Tricyclics Serum Tox Qualitative Application
Beckman Coulter System Parameters, AU5800

Parameters | Specific Test Parameters

General | LIH | ISE | HbA1c | Calculated Test | Range

Test Name: TCACQ ∇ < > Type: Serum ∇ Operation Yes ∇

Sample Volume		7.2 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)	162 µL	Dilution	0 µL	Reagent OD Limit				
	R1-2	µL	Dilution	µL	1st.	Low	-2.00	High	3.00
					Last	Low	-2.00	High	3.00
	R2(R2-1)	54 µL	Dilution	0 µL					
					Dynamic Range	Low	#	High	#
Common Rgt. Type		None	Name		Correlation Factor	A	1	B	0
Wavelength	Pri	340 ∇nm	Sec.	520 ∇nm	Factor for Maker	A	1	B	0
Method		FIXED1* ∇							
Reaction Slope		+ ∇			Onboard Stability Period		32 Day	0 Hour	
Measuring Point1 1st		14	Last	20	LIH Influence Check		∇		
Measuring Point2 1st			Last		Lipemia		∇		
Linearity Limit		%			Icterus		∇		
Lag Time Check		No ∇			Hemolysis		∇		

Parameters | Specific Test Parameters

General | LIH | ISE | HbA1c | Calculated Test | Range

Test Name: TCACQ ∇ < > Type: Serum ∇

Value/Flag: # ∇

Level Low # High †

Specific Ranges:

	Sex	From Year	From Month	To Year	To Month	Low	High
☐ 1.	# ∇	#	#	#	#	#	#
☐ 2.	# ∇	#	#	#	#	#	#
☐ 3.	# ∇	#	#	#	#	#	#
☐ 4.	# ∇	#	#	#	#	#	#
☐ 5.	# ∇	#	#	#	#	#	#
☐ 6.	# ∇	#	#	#	#	#	#
7. Standard demographics						#	#
8. Not within expected values						#	#

Panic Value Low # High # Unit % Decimal Places #

Parameters | Calibration Parameters

Calibrators | Calibration Specific

General | ISE

Test Name: TCACQ ∇ < > Type Serum ∇ Cuvette . ∇

☐ Use Serum Cal.

Calibration Type: AA ∇ Formula: Y=AX+B ∇ Counts: 2 ∇

<Calibrator Parameters>

	Calibrator	OD	Conc	Range Low	Range High
Point 1:	# ∇		0	-99999	999999
Point 2:	# ∇		100	-99999	999999
Point 3:	∇				
Point 4:	∇				
Point 5:	∇				
Point 6:	∇				
Point 7:	∇				
Point 8:	∇				
Point 9:	∇				
Point 10:	∇				

Slope Check + ∇

Allowance Range Check

☐ Reagent Blank

☐ Calibration

Advanced Calibration Operation No ∇

Interval (RB/ACAL) ∇

<Point Cal. For Master Curve> No. of Correction Points ∇ Use Master Curve ∇ ☐ Lot Calibration

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

Stability

Reagent Blank # Day # Hour

Calibration 18 Day 0 Hour

MB Type Factor: 1-Point Calibration Point None ∇ ☐ with Conc-0

User defined

* Can also be run as RATE1

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DRI Tricyclics Serum Tox Semiquantitative Application
Beckman Coulter System Parameters, AU5800

Parameters | Specific Test Parameters
General | LIH | ISE | HbA1c | Calculated Test | Range

Test Name: TCASQ ▽ < > Type: Serum ▽ Operation Yes ▽

Sample Volume		7.2 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)	162 µL	Dilution	0 µL	Reagent OD Limit				
	R1-2	µL	Dilution	µL	1st.	Low	-2.00	High	3.00
					Last	Low	-2.00	High	3.00
	R2(R2-1)	54 µL	Dilution	0 µL					
					Dynamic Range	Low	0	High	1000
Common Rgt. Type		None	Name	None	Correlation Factor	A	1	B	0
Wavelength	Pri	340 ▽nm	Sec.	520 ▽nm	Factor for Maker	A	1	B	0
Method		FIXED1* ▽							
Reaction Slope		+ ▽			Onboard Stability Period		32 Day	0	Hour
Measuring Point1 1st		14	Last	20	LIH Influence Check		# ▽		
Measuring Point2 1st			Last		Lipemia		▽		
Linearity Limit		%			Icterus		▽		
Lag Time Check		No ▽			Hemolysis		▽		

Parameters | Specific Test Parameters
General | LIH | ISE | HbA1c | Calculated Test | Range

Test Name: TCASQ ▽ < > Type: Serum ▽

Value/Flag: # ▽

Level Low # High #

Specific Ranges:

	Sex	From Year	From Month	To Year	To Month	Low	High
☐ 1.	# ▽	#	#	#	#	#	#
☐ 2.	# ▽	#	#	#	#	#	#
☐ 3.	# ▽	#	#	#	#	#	#
☐ 4.	# ▽	#	#	#	#	#	#
☐ 5.	# ▽	#	#	#	#	#	#
☐ 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: TCASQ ▽ < > Type Serum ▽ Cuvette . ▽

☐ Use Serum Cal.

Calibration Type: 5AB ▽ Formula: POLYGONAL ▽ Counts: 2 ▽

<Calibrator Parameters>

	Calibrator	OD	Conc	Range Low	Range High
Point 1:	# ▽		0	-2.00	3.00
Point 2:	# ▽		150	-2.00	3.00
Point 3:	# ▽		300	-2.00	3.00
Point 4:	# ▽		500	-2.00	3.00
Point 5:	# ▽		1000	-2.00	3.00
Point 6:	▽				
Point 7:	▽				
Point 8:	▽				
Point 9:	▽				
Point 10:	▽				

Slope Check + ▽

Allowance Range Check

☐ Reagent Blank

☐ Calibration

Advanced Calibration Operation ▽

Interval (RB/ACAL) ▽

<Point Cal. For Master Curve> No. of Correction Points ▽ Use Master Curve ▽ ☐ Lot Calibration

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

Stability: Reagent Blank # Day # Hour; Calibration 18 Day 0 Hour

MB Type Factor: 1-Point Calibration Point None ▽ ☐ with Conc-0

User defined
* Can also be run as RATE1

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Precision Tests for within-run and total precision, evaluated with packaged reagents, controls and calibrators, yielded the following results (N=80/level):

Controls	Control 1	Control 2	Control 3	Cutoff
Qualitative AU480				
Mean (mA/min)	796	870	923	837
Within-Run SD (mA/min)	3.0	3.0	2.6	2.8
Within-Run CV (%)	0.4%	0.3%	0.3%	0.3%
Total SD (A/min)	3.8	3.6	3.3	4.2
Total CV (%)	0.5%	0.4%	0.4%	0.5%
Qualitative AU640*				
Mean (mA/min)	454	590	N/A	536
Within-Run SD(mA/min)	3.1	3.6	N/A	4.4
Within-Run CV (%)	0.7%	0.6%	N/A	0.8%
Total SD (mA/min)	4.1	4.8	N/A	5.2
Total CV (%)	0.9%	0.8%	N/A	1.0%
Qualitative AU680				
Mean (mA/min)	786	862	913	833
Within-Run SD (mA/min)	5.7	5.7	6.1	6.2
Within-Run CV (%)	0.7%	0.7%	0.7%	0.7%
Total SD (mA/min)	31.6	27.5	31.8	24.8
Total CV (%)	4.0%	3.2%	3.5%	3.0%
Qualitative AU5800				
Mean (mA/min)	771	844	897	811
Within-Run SD (mA/min)	11.4	12.3	12.0	10.9
Within-Run CV (%)	1.5%	1.5%	1.3%	1.3%
Total SD (mA/min)	11.5	12.5	12.3	11.2
Total CV (%)	1.5%	1.5%	1.4%	1.4%

Controls	Control 1	Control 2	Control 3	Cutoff
Semiquantitative AU480				
Mean (ng/mL)	225	439	786	300
Within-Run SD (ng/mL)	5.2	12.9	19.0	7.8
Within-Run CV (%)	2.3%	2.9%	2.4%	2.6%
Total SD (ng/mL)	6.0	15.7	25.7	9.7
Total CV (%)	2.7%	3.6%	3.3%	3.2%
Semiquantitative AU640*				
Mean (ng/mL)	158	548	N/A	317
Within-Run SD (ng/mL)	6.0	31.0	N/A	14.2
Within-Run CV (%)	3.8%	5.7%	N/A	4.5%
Total SD (ng/mL)	7.8	39.4	N/A	16.9
Total CV (%)	4.9%	7.2%	N/A	5.3%
Semiquantitative AU680				
Mean (ng/mL)	218	434	808	302
Within-Run SD (ng/mL)	9.1	29.3	50.6	17.0
Within-Run CV (%)	4.2%	6.7%	6.3%	5.6%
Total SD (ng/mL)	16.5	41.4	63.2	19.8
Total CV (%)	7.5%	9.5%	7.8%	6.6%
Semiquantitative AU5800				
Mean (ng/mL)	224	436	777	300
Within-Run SD (ng/mL)	11.3	23.6	40.2	12.6
Within-Run CV (%)	5.1%	5.4%	5.2%	4.2%
Total SD (ng/mL)	12.1	26.3	45.7	14.8
Total CV (%)	5.4%	6.0%	5.9%	4.9%

AU640* N=60/level

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Accuracy and Correlation AU480, AU680, and AU5800

Patient samples were assayed using the DRI Tricyclics Serum Tox Assay on the Beckman Coulter AU480, AU680, and AU5800, and tested against the reference analyzer, the Hitachi 717.

Qualitative Method Comparison			
	Positive Agreement (%)	**Negative Agreement (%)**	**Total Agreement (%)**
AU480	90.2%	100.0%	96.4%
AU680	97.6%	97.1%	97.3%
AU5800	95.8%	98.9%	97.9%

DRI Tricyclics Serum Tox Assay Qualitative Method Comparison

		Hitachi 717 +	Hitachi 717 -
AU480	+	46	0
	-	5	89

		Hitachi 717 +	Hitachi 717 -
AU680	+	41	2
	-	1	66

		Hitachi 717 +	Hitachi 717 -
AU5800	+	46	1
	-	2	91

Semiquantitative Method Comparison			
	Positive Agreement (%)	**Negative Agreement (%)**	**Total Agreement (%)**
AU480	97.8%	96.8%	97.1%
AU680	93.5%	100.0%	97.3%
AU5800	95.7%	100.0%	98.2%

DRI Tricyclics Serum Tox Assay Semiquantitative Method Comparison

		Hitachi 717 +	Hitachi 717 -
AU480	+	44	3
	-	1	92

		Hitachi 717 +	Hitachi 717 -
AU680	+	43	0
	-	3	64

		Hitachi 717 +	Hitachi 717 -
AU5800	+	44	0
	-	2	64

AU640 Accuracy and Correlation

The AU640 data is presented as being representative of the performance of this instrument family.

One hundred twenty seven (127) serum samples were assayed in qualitative mode using the DRI Tricyclics Serum Tox Assay on the Beckman AU640 and the Hitachi 717 analyzers. A Sensitivity of 100% (89 of 89 positive samples) and a Specificity of 98% (50 of 51 negative samples) were observed between the two analyzers.

A linear regression analysis of the semi-quantitative data yielded the following results:
Beckman AU640 = 1.04 (Hitachi 717) – 6.7, with a correlation coefficient of 0.950

End

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