

DRI[®] BENZODIAZEPINE SERUM TOX APPLICATION
Beckman Coulter AU400[®], AU480[®], AU640[®], AU680[®],
AU2700[®], AU5400[®], AU5800[®]



Catalog No. 0920

The DRI Benzodiazepine Serum Tox Assay is intended for the qualitative and semiquantitative determination of benzodiazepines in human serum or plasma.

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 Benzodiazepine Serum Tox Kit	R1 25 mL R2 8 mL	0920
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
U.S. Toll free fax: (888) 527-8001 / Fax: (510) 979-5420

Microgenics GmbH, Spitalhofstrasse 94, 94032 Passau, Germany

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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.

**Results and
Data
Interpretation**

Results for samples will be printed in ng/mL.

DRI Benzodiazepine Serum Tox Qualitative Application

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

Specific Test Parameters											
General		LIH	ISE	Range							
Test Name:	SBENZQ ▾			<	>	Type:	Serum ▾		Operation:	Yes ▾	
Sample:	Volume	4.0	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	
Wavelength:	Pri.	340	▾	Sec.	520	▾	Reagent OD limit:	First L	-2.00	First H	2.50
Method:	FIXED1* ▾						Last L	-2.00	Last H	2.50	
Reaction slope:	+ ▾						Dynamic Range:	L	#	H	#
Measuring Point 1:	First	14		Last	20		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:	SBENZQ ▾			<	>	Type:	Serum ▾			
Value/Flag:	# ▾		Level L:	# ▾		Level H:	† ▾			
Normal Ranges:	Age L		Age H		L		H			
	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.	# ▾	#	#	#	#	#	#	#	#	#
<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:	SBENZQ ▾			<	>	Type:	Serum ▾			
Calibration Type:	AA ▾		Formula:	Y=AX+B ▾		Counts:	2		Process:	CONC ▾
Point 1:	Cal. No.	#	OD		CONC	0	Factor/OD-L	-99999	Factor/OD-H	99999
Point 2:	Cal. No.	#			100		-99999	99999		
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 RATE1

DRI Benzodiazepine Serum Tox Semiquantitative Application

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

Specific Test Parameters	
General	LIH ISE Range
Test Name:	SBENSQ < > Type: Serum Operation: Yes
Sample:	Volume: 4.0 μ L Dilution: 0 μ L Pre-Dilution Rate: 1
Reagents:	R1 Volume: 180 μ L Dilution: 0 μ L Min OD Max OD
	R2 Volume: 60 μ L Dilution: 0 μ L L: -2.00 H: 2.50
Wavelength:	Pri.: 340 Sec.: 520 Reagent OD limit: First L: -2.00 First H: 2.50
Method:	FIXED1* Last L: -2.00 Last H: 2.50
Reaction slope:	+
Measuring Point 1:	First: 14 Last: 20 L: 0 H: 200
Measuring Point 2:	First: Last: Correlation Factor: A: 1.0000 B: 0.0000
Linearity:	% On-board stability period: #
No Lag Time:	No

Specific Test Parameters	
General	LIH ISE Range
Test Name:	SBENSQ < > Type: Serum
Value/Flag:	# Level L: # Level H: #
Normal Ranges:	Age L: Age H: L: 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:	SBENSQ < > Type: Serum
Calibration Type:	5AB Formula: EIA TYPE 1 Counts: 2 Process: CONC
Point 1:	Cal. No.: # OD: CONC: 0 Factor/OD-L: -2.0000 Factor/OD-H: 2.5000
Point 2:	# # # 25 -2.0000 2.5000
Point 3:	# # # 50 -2.0000 2.5000
Point 4:	# # # 100 -2.0000 2.5000
Point 5:	# # # 200 -2.0000 2.5000
Point 6:	# # # # #
Point 7:	# # # # #
1-Point Cal. Point:	# <input type="checkbox"/> With CONC-0 Slope Check: + Advanced Calibration: #
MB Type Factor:	Calibration Stability Period: #

*Can also be run as RATE1
User defined

DRI Benzodiazepine Serum Tox Qualitative Application

Beckman Coulter System Parameters, AU480/AU680

Specific Test Parameters	
General	ISE Range
Test Name: SBENZQ	Type: Serum
Sample Volume: 3.6 μ L	Dilution: 0 μ L
Pre-Dilution Rate: 1	OD Limit: Min. OD: -2.00 Max. OD: 3.00
Reagents Volume: R1(R1-1) 162 μ L	Dilution: 0 μ L
	Reagent OD limit: First Low: -2.00 High: 3.00
	Last Low: -2.00 High: 3.00
R2 (R2-1) 54 μ L	Dilution: 0 μ L
	Dynamic Range Low: # High: #
Wavelength: Pri. 340 nm	Sec. 520 nm
Method: FIXED1*	Correlation Factor A: 1 B: 0
Reaction slope: +	Factor for Maker A: 1 B: 0
Measuring Point 1: First 14 Last 20	Onboard Stability: 29 Days 0 Hour
Measuring Point 2: First Last	LIH Influence Check: <input type="checkbox"/>
Linearity: %	Lipemia: <input type="checkbox"/>
No Lag Time: No	Icterus: <input type="checkbox"/>
	Hemolysis: <input type="checkbox"/>

Specific Test Parameters	
General	ISE Range
Test Name: SBENZQ	Type: Serum
Value/Flag: #	Level L: -999999 Level H: †
Specific Ranges:	Panic Value
From To	Low High
<input type="checkbox"/> 1. Sex Year Month Year Month Low High	<input type="checkbox"/> # #
<input type="checkbox"/> 2. # # # # # # # #	<input type="checkbox"/> # #
<input type="checkbox"/> 3. # # # # # # # #	<input type="checkbox"/> # #
<input type="checkbox"/> 4. # # # # # # # #	<input type="checkbox"/> # #
<input type="checkbox"/> 5. # # # # # # # #	<input type="checkbox"/> # #
<input type="checkbox"/> 6. # # # # # # # #	<input type="checkbox"/> # #
7. No demographics	<input type="checkbox"/> # #
8. Not within expected values	<input type="checkbox"/> # #
Unit: %	Decimal Places: #

Calibration Specific	
General	ISE
Test Name: SBENZQ	Type: Serum
Calibration Type: AA	Formula: Y=AX+B
Counts: 2	Process: CONC
Point 1: Cal. No. # OD CONC 0 Factor/OD-L -99999 Factor/OD-H 999999	
Point 2: Cal. No. # OD CONC 100 Factor/OD-L -99999 Factor/OD-H 999999	
Point 3: Cal. No. # OD CONC Factor/OD-L Factor/OD-H	
Point 4: Cal. No. # OD CONC Factor/OD-L Factor/OD-H	
Point 5: Cal. No. # OD CONC Factor/OD-L Factor/OD-H	
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: <input type="checkbox"/>
MB Type Factor: <input type="checkbox"/>	Calibration Stability Period: #

User defined
 * Can also be run as RATE1

DRI Benzodiazepine Serum Tox Semiquantitative Application

Beckman Coulter System Parameters, AU480/AU680

Specific Test Parameters

General LIH ISE Range

Test Name: SBENSQ < > Type: Serum Operation: Yes

Sample Volume: 3.6 µL Dilution: 0 µL OD Limit: Min. OD: -2.0000 Max. 3.0000

Pre-Dilution Rate: 1

Reagents Volume: R1(R1-1) 162 µL Dilution: 0 µL Reagent OD limit: First Low: -2.0000 High: 3.0000 Last Low: -2.0000 High: 3.0000

R2 (R2-1) 54 µL Dilution: 0 µL Dynamic Range Low: 0 High: 200

Correlation Factor A: 1 B: 0

Factor for Maker A: 1 B: 0

Wavelength: Pri. 340 nm Sec. 520 nm

Method: FIXED1*

Reaction slope: +

Onboard Stability: 29 Days 0 Hour

Measuring Point 1: First 14 Last 20 LIH Influence Check: #

Measuring Point 2: First Last

Linearity: %

No Lag Time: No

Lipemia Icterus Hemolysis

Specific Test Parameters

General ISE Range

Test Name: SBENSQ < > Type: Serum

Value/Flag: # Level L: # Level H: #

Specific Ranges:

	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. No demographics						#	#
8. Not within expected values						#	#

Unit: ng/mL Decimal Places: #

Panic Value: Low # High #

Calibration Specific

General ISE

Test Name: SBENSQ < > Type: Serum Use Serum Cal.

Calibration Type: 5AB Formula: POLYGONAL Counts: 2

<Calibrator Parameters>

Calibrator ↑	OD	Conc	Factor Range	Low	High
Point 1:	#	0	-2.0000	3.0000	
Point 2:	#	25	-2.0000	3.0000	
Point 3:	#	50	-2.0000	3.0000	
Point 4:	#	100	-2.0000	3.0000	
Point 5:	#	200	-2.0000	3.0000	
Point 6:					
Point 7:					
Point 8:					
Point 9:					
Point 10:					

Slope Check: +

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	High
Point 1:					
Point 2:					

Stability: Reagent Blanks: # Day # Hour Calibration: 24 Day 0 Hour

MB Type Factor: 1-Point Calibration Point: None With CONC-0

*Can also be run as RATE1
#User-defined values

DRI Benzodiazepine Serum Tox Qualitative Application

Beckman Coulter System Parameters, AU5800

Parameters		Specific Test Parameters					
General	LIH	ISE	HbA1c	Calculated Test	Range		
Test Name:		SBENZQ	<	>	Type: Serum	Operation: Yes	
Sample Volume	3.6	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	1 st : Low: -2.00 High: 3.00
	R2(R2-1)	54	μL	Dilution	0	μL	Last: Low: -2.00 High: 3.00
Common Rgt. Type	None		Name			Dynamic Range Low: # High: #	
Wavelength	Pri	340	▽nm	Sec.	520	▽nm	Correlation Factor A: 1 B: 0
Method	FIXED1*				Factor for Maker A: 1	B: 0	
Reaction Slope	+				Onboard Stability Period: 29 Day # Hour		
Measuring Point1 1 st	14		Last	20		LIH Influence Check: ▽	
Measuring Point2 1 st			Last			Lipemia: ▽	
Linearity Limit					Icterus: ▽		
Lag Time Check	No				Hemolysis: ▽		

Parameters		Specific Test Parameters						
General	LIH	ISE	HbA1c	Calculated Test	Range			
Test Name:		SBENZQ	<	>	Type: Serum			
Value/Flag:		#						
Level		Low	#	High	†			
Specific Ranges:								
	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	#

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

User defined
 * Can also be run as RATE1

DRI Benzodiazepine Serum Tox Semiquantitative Application

Beckman Coulter System Parameters, AU5800

Parameters		Specific Test Parameters								
General	LIH	ISE	HbA1c		Calculated Test	Range				
Test Name:		SBENSQ	<	>	Type:	Serum	Operation	Yes		
Sample Volume	3.6	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	1 st .	Low	-2.00	
							Last	Low	-2.00	
	R2(R2-1)	54	μL	Dilution	0	μL		High	3.00	
Common Rgt. Type	None		Name			Dynamic Range Low	0	High	200	
Wavelength	Pri	340	∇nm	Sec.	520	∇nm	Correlation Factor A	1	B	0
Method	FIXED1*					Factor for Maker A	1	B	0	
Reaction Slope	+					Onboard Stability Period	29	Day	0	Hour
Measuring Point1 1 st	14		Last	20		LIH Influence Check	#	∇		
Measuring Point2 1 st			Last			Lipemia		∇		
Linearity Limit						Icterus		∇		
Lag Time Check	No					Hemolysis		∇		

Parameters		Specific Test Parameters						
General	LIH	ISE	HbA1c		Calculated Test	Range		
Test Name:		SBENSQ	<	>	Type:	Serum	∇	
Value/Flag:		#	Level		Low	#	High	#
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.	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:		SBENSQ	<	>	Type:	Serum	Cuvette .	∇	
		<input type="checkbox"/> Use Serum Cal.							
Calibration Type:		5AB	Formula:	POLYGONAL	Counts:	2			
<Calibrator Parameters>		Range				Slope Check			
Point 1:	Calibrator	OD	Conc	Low	High	+ ∇			
Point 2:	#		0	-2.0	3.0	Allowance Range Check			
Point 3:	#		25	-2.0	3.0	<input type="checkbox"/> Reagent Blank			
Point 4:	#		50	-2.0	3.0	<input type="checkbox"/> Calibration			
Point 5:	#		100	-2.0	3.0	Advanced Calibration			
Point 6:			200	-2.0	3.0	Operation			
Point 7:						No ∇			
Point 8:						Interval (RB/ACAL)			
Point 9:						∇			
Point 10:						<input type="checkbox"/> Lot Calibration			
<Point Cal. For	No. of Correction Points			Use Master Curve					
Master Curve>		OD Range				Stability			
Point-1	Calibrator	OD	Conc	Low	High	Reagent Blank	#	Day	#
Point-2						Calibration	24	Day	0
MB Type Factor:	1-Point Calibration Point				<input type="checkbox"/> with Conc-0				

User-defined values
*Can also be run as RATE1

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)	594	724	782	641
Within-Run SD (mA/min)	2.4	2.3	1.8	2.0
Within-Run CV (%)	0.4%	0.3%	0.2%	0.3%
Total SD (A/min)	4.1	5.3	5.5	4.6
Total CV (%)	0.7%	0.7%	0.7%	0.7%
Qualitative AU640*				
Mean (mA/min)	491	645	N/A	531
Within-Run SD(mA/min)	4.0	4.7	N/A	3.6
Within-Run CV (%)	0.8%	0.7%	N/A	0.7%
Total SD (mA/min)	4.3	5.9	N/A	4.4
Total CV (%)	0.9%	0.9%	N/A	0.8%
Qualitative AU680				
Mean (mA/min)	625	757	822	674
Within-Run SD (mA/min)	4.3	4.9	4.3	5.1
Within-Run CV (%)	0.7%	0.7%	0.5%	0.8%
Total SD (mA/min)	35.5	34.4	42.8	36.5
Total CV (%)	5.7%	4.5%	5.2%	5.4%
Qualitative AU5800				
Mean (mA/min)	626	755	822	675
Within-Run SD (mA/min)	9.2	8.9	8.9	8.3
Within-Run CV (%)	1.5%	1.2%	1.1%	1.2%
Total SD (mA/min)	37.7	36.9	46.0	37.3
Total CV (%)	6.0%	4.9%	5.6%	5.5%

Controls	Control 1	Control 2	Control 3	Cutoff
Semiquantitative AU480				
Mean (ng/mL)	37	94	188	50
Within-Run SD (ng/mL)	0.7	1.2	3.4	0.9
Within-Run CV (%)	1.8%	1.3%	1.8%	1.8%
Total SD (ng/mL)	1.2	2.0	5.6	1.8
Total CV (%)	3.2%	2.1%	3.0%	3.7%
Semiquantitative AU640*				
Mean (ng/mL)	23	99	N/A	46
Within-Run SD (ng/mL)	1.7	2.7	N/A	2.1
Within-Run CV (%)	7.2%	2.8%	N/A	4.6%
Total SD (ng/mL)	1.8	3.6	N/A	2.5
Total CV (%)	7.7%	3.6%	N/A	5.5%
Semiquantitative AU680				
Mean (ng/mL)	36	94	193	51
Within-Run SD (ng/mL)	1.2	3.3	7.7	2.1
Within-Run CV (%)	3.3%	3.5%	4.0%	4.1%
Total SD (ng/mL)	1.7	4.4	10.6	3.0
Total CV (%)	4.6%	4.7%	5.5%	5.9%
Semiquantitative AU5800				
Mean (ng/mL)	36	94	191	52
Within-Run SD (ng/mL)	1.4	2.0	6.2	1.4
Within-Run CV (%)	3.8%	2.1%	3.2%	2.7%
Total SD (ng/mL)	1.5	2.6	9.5	2.3
Total CV (%)	4.2%	2.8%	5.0%	4.4%

AU640* N=60/level

Accuracy and Correlation AU480, AU680, and AU5800

Patient samples were assayed using the DRI Benzodiazepine 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	98.0%	100.0%	99.0%
AU680	100.0%	100.0%	100.0%
AU5800	96.0%	100.0%	98.0%

DRI Benzodiazepine Serum Tox Assay Qualitative Method Comparison

		Hitachi 717				Hitachi 717				Hitachi 717	
		+	-			+	-			+	-
AU480	+	49	0	AU680	+	50	0	AU5800	+	48	0
	-	1	50		-	0	50		-	2	50

Semiquantitative Method Comparison

	Positive Agreement (%)	Negative Agreement (%)	Total Agreement (%)
AU480	97.5%	98.6%	98.2%
AU680	97.6%	98.5%	98.2%
AU5800	100.0%	97.1%	98.2%

DRI Benzodiazepine Serum Tox Assay Semiquantitative Method Comparison

		Hitachi 717				Hitachi 717				Hitachi 717	
		+	-			+	-			+	-
AU480	+	39	1	AU680	+	41	1	AU5800	+	40	2
	-	1	69		-	1	67		-	0	68

AU640 Accuracy and Correlation

One hundred forty nine (149) serum samples were assayed in the qualitative mode using the DRI Benzodiazepine Serum Tox Enzyme Immunoassay on the Beckman AU640 and the Hitachi 717 analyzers. A Sensitivity of 100% (99 of 99 positive samples) and a Specificity of 100% (50 of 50 negative samples) were observed between the two analyzers.

A linear regression analysis of the semiquantitative data yielded the following results: Beckman AU640 = 1.19 (Hitachi 717) – 107.2, with a correlation coefficient of 0.953

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