



DRI[®] Benzodiazepine Serum Tox Assay Application – BECKMAN COULTER^{*} UniCel^{*} DxC and Synchron^{*} Systems

Beckman Coulter Reorder Number A45323

Homogeneous enzyme immunoassay for the qualitative or semi-quantitative determination of Benzodiazepines in human serum, plasma.

For In Vitro Diagnostic Use Only

Intended Use **The information provided here is intended as a supplement to the reagent insert. Please refer to the package insert for: intended use, reagent storage, reagent preparation, specimen collection, specimen storage, quality control, and additional performance data.**

Ordering Information The following materials are available from your local Beckman Coulter Representative:

Item	Beckman Coulter Reorder Number
DRI [®] Benzodiazepine Serum Tox Assay Kit (25 mL / 8 mL)	A45323
DRI [®] Serum Tox Negative Calibrator (10 mL)	A45326
DRI [®] Serum Tox Calibrator 1 (5 mL)	A45327
DRI [®] Serum Tox Calibrator 2 (5 mL)	A45328
DRI [®] Serum Tox Calibrator 3 (5 mL)	A45331
DRI [®] Serum Tox Calibrator 4 (5 mL)	A45332
User-Defined Reagent Cartridge (pkg. of 12)	442835

For Technical Support please contact your local Beckman Coulter Representative.

DRI[®] is a registered trademark of Microgenics.

* Synchron CX, Synchron LX and UniCel DxC are registered trademark of Beckman Coulter Inc., Fullerton, CA 92835

Reagent Storage

Please refer to the reagent insert for information on reagent storage.

NOTE:

It is not recommended to leave the reagent on-board Synchron CX for more than 30 days and on-board Synchron LX/UniCel DxC for more than 60 days.

Procedure for Analyzer

Please refer to the operator's manuals for information on analyzer operation. Dispense Antibody/Substrate Reagent and Enzyme Conjugate Reagent into appropriate compartments of a User Defined Cartridge (PN 442835) as shown in the table below. Store unused portion in bottles.

	User Defined Cartridge	
DRI[®] Benzodiazepine Assay Kit	Compartment B	Compartment C
Antibody/Substrate Reagent	12.5 mL	
Enzyme Conjugate Reagent		4 mL

Calibration Frequency

Please refer to the reagent package insert for information on calibration. To monitor qualitatively or semi-quantitatively, calibration shall be performed every 14 days or as indicated by control recovery.

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Application Parameters

Parameters The following tables outline the DRI Benzodiazepine Serum Tox Assay chemistry parameters for **qualitative** mode on the UniCel DxC and SYNCHRON LX analyzers.

Number [*] Chem [SBZX] <F3 UDR+>

Chemistry Parameters		Page 1 of 3	
Reaction Type	[Rate 1]		
Units	[mA/min]		
Precision	[X.X]		
Reaction Direction	[Positive]		
Math Model	[DAT]		
Primary Wavelength	[340]		
Secondary Wavelength	[650]		
Calculation Factor	[1000]		
No. of Calibrators	[3]		
Setpoints	1 [0.0]	4 []	
	2 [50.0]	5 []	
	3 [200.0]	6 []	
Cal Time Limit	[336] hours		
Cal Save	[√]		

Processing Parameters		Page 2 of 3	
First Inject	Component	[B]	
	Dispense Volume	[210] µL	
Second Inject	Component	[None]	
	Dispense Volume	[]	
	Inject Time	[] sec	
Third Inject	Component	[C]	
	Dispense Volume	[70] µL	
	Inject Time	[276] sec	
Sample Volume	[5] µL		
ORDAC Volume	[] µL		
Blank	Start Read	[292] sec	
	End Read	[308] sec	
Initial (DxC only)	Start Read	[] sec	
	End Read	[] sec	
Reaction 1	Start Read	[336] sec	
	End Read	[396] sec	
Reaction 2	Start Read	[] sec	
	End Read	[] sec	

Error Detection Limits		Page 3 of 3	
Blank	ABS Low/High Limits	[-1.500]/[2.200]	
	Rate Low/High Limits	[-1.500]/[2.200]	
	Mean Deviation	[2.200]	
Reaction 1	ABS Low/High Limits	[-1.500]/[2.200]	
	Rate Low/High Limits	[-1.500]/[2.200]	
	Mean Deviation	[2.200]	
Reaction 2	ABS Low/High Limits	[-1.500]/[2.200]	
	Rate Low/High Limits	[-1.500]/[2.200]	
	Mean Deviation	[2.200]	
Substrate Depletion			
	Initial Rate	[99.999]	
	Delta ABS	[2.200]	
Multipoint Span			
	1-2	[0.000]	[]
		[]	[]
		[]	[]
Usable Result Range			
	Low Limit	[0.000]	
	High Limit	[99999.999]	
ORDAC			
	Low Limit	[]	
	High Limit	[]	

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Application Parameters

Parameters

The following tables outline the DRI Benzodiazepine Serum Tox Assay chemistry parameters for **qualitative** mode on the SYNCHRON CX analyzer.

Number [*] Chem [SBZX] <F3 UDR+>

Chemistry Parameters		Page 1 of 3	
Reaction Type	[Rate 1]		
Units	[ng/mL]		
Precision	[X.X]		
Reaction Direction	[Positive]		
Math Model	[Linear]		
Primary Wavelength	[340]		
Secondary Wavelength	[650]		
Calculation Factor	[0]		
No. of Calibrators	[2]		
Setpoints	1	[0.0]	4 []
	2	[50.0]	5 []
	3	[]	6 []
Cal Time Limit	[336] hours		

Processing Parameters		Page 2 of 3	
First Inject	Component	[B]	
	Dispense Volume	[210] µL	
Second Inject	Component	[None]	
	Dispense Volume	[]	
	Inject Time	[]	
Third Inject	Component	[C]	
	Dispense Volume	[70]	
	Inject Time	[368]	
Sample Volume	[5] µL		
ORDAC Volume	[] µL		
Reagent Blank	Start Read	[237] sec	
	End Read	[300] sec	
Reaction	Start Read	[96] sec	
	End Read	[144] sec	
Usable Result Range			
	Low Limit	[0.000]	
	High Limit	[99999.999]	

Error Detection Limits		Page 3 of 3	
Reagent Blank	ABS Low/High Limits	[-1.500]/[1.500]	
Reaction	ABS Low/High Limits	[-1.500]/[1.500]	
Substrate Depletion			
	Initial Rate	[99.999]	
	Delta ABS	[1.500]	
Multipoint Span			
	1-2	[0.000]	[]
		[]	[]
		[]	[]

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Application Parameters

Parameters The following tables outline the DRI Benzodiazepine Serum Tox Assay chemistry parameters for **semi-quantitative** mode on the UniCel DxC and SYNCHRON LX analyzers.

Number [*] Chem [SBZX] <F3 UDR+>

Chemistry Parameters		Page 1 of 3	
Reaction Type	[Rate 1]		
Units	[ng/mL]		
Precision	[X.X]		
Reaction Direction	[Positive]		
Math Model	[1]		
Primary Wavelength	[340]		
Secondary Wavelength	[650]		
Calculation Factor	[1]		
No. of Calibrators	[5]		
Setpoints	1 [0.0]	4 [100.0]	
	2 [25.0]	5 [200.0]	
	3 [50.0]	6 []	
Cal Time Limit	[336] hours		
Cal Save	[√]		

Processing Parameters		Page 2 of 3	
First Inject	Component	[B]	
	Dispense Volume	[210] µL	
Second Inject	Component	[None]	
	Dispense Volume	[]	
	Inject Time	[] sec	
Third Inject	Component	[C]	
	Dispense Volume	[70] µL	
	Inject Time	[276] sec	
Sample Volume	[5] µL		
ORDAC Volume	[] µL		
Blank	Start Read	[292] sec	
	End Read	[308] sec	
Initial (DxC only)	Start Read	[] sec	
	End Read	[] sec	
Reaction 1	Start Read	[336] sec	
	End Read	[396] sec	
Reaction 2	Start Read	[] sec	
	End Read	[] sec	

Error Detection Limits		Page 3 of 3	
Blank	ABS Low/High Limits	[-1.500]/[2.200]	
	Rate Low/High Limits	[-1.500]/[2.200]	
	Mean Deviation	[2.200]	
Reaction 1	ABS Low/High Limits	[-1.500]/[2.200]	
	Rate Low/High Limits	[-1.500]/[2.200]	
	Mean Deviation	[2.200]	
Reaction 2	ABS Low/High Limits	[-1.500]/[2.200]	
	Rate Low/High Limits	[-1.500]/[2.200]	
	Mean Deviation	[2.200]	
Substrate Depletion			
	Initial Rate	[99.999]	
	Delta ABS	[2.200]	
Multipoint Span			
	1-2	[0.009]	[0.005]
		[0.005]	[0.037]
		[0.018]	[]
Usable Result Range			
	Low Limit	[0.000]	
	High Limit	[1000.0]	
ORDAC			
	Low Limit	[]	
	High Limit	[]	

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Application Parameters

Parameters

The following tables outline the DRI Benzodiazepine Serum Tox Assay chemistry parameters for **semi-quantitative** mode on the SYNCHRON CX analyzer.

Number [*] Chem [SBZX] <F3 UDR+>

Chemistry Parameters		Page 1 of 3	
Reaction Type	[Rate 1]		
Units	[ng/mL]		
Precision	[X.X]		
Reaction Direction	[Positive]		
Math Model	[1]		
Primary Wavelength	[340]		
Secondary Wavelength	[650]		
Calculation Factor	[0]		
No. of Calibrators	[5]		
Setpoints	1	[0.0]	4 [100.0]
	2	[25.0]	5 [200.0]
	3	[50.0]	6 []
Cal Time Limit	[336] hours		

Processing Parameters		Page 2 of 3	
First Inject	Component	[B]	
	Dispense Volume	[210] µL	
Second Inject	Component	[None]	
	Dispense Volume	[]	
	Inject Time	[]	
Third Inject	Component	[C]	
	Dispense Volume	[70]	
	Inject Time	[368]	
Sample Volume	[5] µL		
ORDAC Volume	[] µL		
Reagent Blank	Start Read	[237] sec	
	End Read	[300] sec	
Reaction	Start Read	[96] sec	
	End Read	[144] sec	
Usable Result Range	Low Limit	[0.000]	
	High Limit	[1000.0]	

Error Detection Limits		Page 3 of 3	
Reagent Blank	ABS Low/High Limits	[-1.500]/[1.500]	
Reaction	ABS Low/High Limits	[-1.500]/[1.500]	
Substrate Depletion			
	Initial Rate	[99.999]	
	Delta ABS	[1.500]	
Multipoint Span			
	1-2	[0.009]	4-5 [0.006]
	2-3	[0.005]	5-1 [0.038]
	3-4	[0.018]	[]

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Results and Data Interpretation

Refer to the package insert for information on specific performance characteristics.

Sensitivity

The table below presents the sensitivity results generated from Synchron instruments:

	CX	DxC	LX
Sensitivity	2.5 ng/mL	2.2 ng/mL	0.9 ng/mL

Typical Precision

Instrument operated and maintained according to the manufacturer's instructions should exhibit a Qualitative within-run coefficient of variation of $\leq 5.0\%$ for all sample levels. The following precision values were recovered using CLSI protocol:

Within-run Precision (Qualitative)

	CX			DxC			LX		
	Mean (mA/min)	SD	%CV	Mean (mA/min)	SD	%CV	Mean (mA/min)	SD	%CV
Serum Tox Cal 1 (25 ng/mL)	159.9	1.23	0.77	167.3	1.23	0.74	168.6	1.41	0.84
Cutoff Calibrator (50 ng/mL)	180.2	1.15	0.64	190.7	1.95	1.02	191.7	1.94	1.01
Serum Tox Cal 3 (100 ng/mL)	215.3	1.13	0.53	223.7	1.37	0.61	224.1	1.66	0.74

Total Run Precision (Qualitative)

	CX			DxC			LX		
	Mean (mA/min)	SD	%CV	Mean (mA/min)	SD	%CV	Mean (mA/min)	SD	%CV
Serum Tox Cal 1 (25 ng/mL)	159.9	1.82	1.14	167.31	3.31	1.87	168.6	3.83	2.27
Cutoff Calibrator (50 ng/mL)	180.2	2.89	1.6	190.7	5.59	2.93	191.7	5.71	2.98
Serum Tox Cal 3 (100 ng/mL)	215.3	2.89	1.34	223.7	4.27	1.91	224.1	3.92	1.75

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Results and Data Interpretation, continued

Within-run Precision (Semi-quantitative)

	CX			DxC			LX		
	Mean (ng/mL)	SD	%CV	Mean (ng/mL)	SD	%CV	Mean (ng/mL)	SD	%CV
Serum Tox Cal 1 (25 ng/mL)	26.9	1.15	4.26	26.1	0.97	3.71	27.0	1.43	5.29
Cutoff Calibrator (50 ng/mL)	47.6	1.40	2.95	47.9	1.80	3.75	48.4	1.73	3.57
Serum Tox Cal 3 (100 ng/mL)	105.0	3.64	3.46	109.2	5.84	5.35	104.5	4.57	4.38

Total Precision (Semi-quantitative)

	CX			DxC			LX		
	Mean (ng/mL)	SD	%CV	Mean (ng/mL)	SD	%CV	Mean (ng/mL)	SD	%CV
Serum Tox Cal 1 (25 ng/mL)	26.9	1.44	5.37	26.1	1.57	6.01	27.0	2.26	8.39
Cutoff Calibrator (50 ng/mL)	47.6	1.89	3.96	47.9	3.18	6.65	48.4	3.51	7.26
Serum Tox Cal 3 (100 ng/mL)	105.0	4.47	4.26	109.2	10.1	9.22	104.5	9.37	8.97

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Results and Data Interpretation, continued

Cross Reactivity

The following various benzodiazepines and structurally related compounds produce **positive** results on UniCel and Synchron Systems at the specified concentrations.

Refer to the Specificity section of the Product Insert for cross reactivity of compounds that are structurally unrelated but used concurrently with benzodiazepines.

Cross-Reactant	Tested Concentration (ng/mL)
Cutoff Calibrator Diazepam	50
Alprazolam	50
Bromazepam	4000
Chlordiazepoxide	20000
Clonazepam	1000
Clorazepate	150
Delorazepam	2000
Desalkylflurazepam	50
Diazepam	50
Flunitrazepam	50
Flurazepam	250
Halazepam	125
Lorazepam	2000
Medazepam	150
Nitrazepam	300
Norclordiazepoxide	20000
Nordiazepam	100
Oxazepam	1000
Oxazolam	10000
Prazepam	50
Temazepam	100
Triazolam	150

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Results and Data Interpretation, continued

Method

Comparison

A total of 162 serum samples were tested in the Qualitative and Semi-quantitative modes on the Synchron and UniCel systems and compared with the results from a Hitachi 717.

The results of concordance studies are presented in the tables below.

Qualitative-serum:

		CX	
		+	-
H717	+	60	0
	-	0	102
Positive Sample Agreement		100%	
Negative Sample Agreement		100%	
Total Sample Agreement		100%	

		DxC	
		+	-
H717	+	60	0
	-	0	102
Positive Sample Agreement		100%	
Negative Sample Agreement		100%	
Total Sample Agreement		100%	

		LX	
		+	-
H717	+	60	0
	-	0	102
Positive Sample Agreement		100%	
Negative Sample Agreement		100%	
Total Sample Agreement		100%	

Semi-quantitative-serum:

		CX	
		+	-
H717	+	60	0
	-	0	102
Positive Sample Agreement		100%	
Negative Sample Agreement		100%	
Total Sample Agreement		100%	

		DxC	
		+	-
H717	+	60	0
	-	0	102
Positive Sample Agreement		100%	
Negative Sample Agreement		100%	
Total Sample Agreement		100%	

		LX	
		+	-
H717	+	60	0
	-	0	102
Positive Sample Agreement		100%	
Negative Sample Agreement		100%	
Total Sample Agreement		100%	

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ADDITIONAL INFORMATION

This guideline has undergone limited technical evaluation and is intended to provide guidance only for the use of this reagent on the UniCel[®] Dx_C, SYNCHRON LX[®] and CX[®] Clinical Systems. You should perform additional testing before reporting diagnostic results.

Information on sample preparation, expected values, quality control, as well as warnings and precautions related to the use of this reagent may be obtained from the package insert.

Instrument operating instructions are contained in the SYNCHRON LX Operations Manual, SYNCHRON CX Operating Instructions, and UniCel Dx_C Systems Instructions For Use (IFU) Manual.

Since Beckman Coulter does not manufacture the reagent or perform quality control or other tests on individual lots, Beckman Coulter cannot be responsible for the quality of the data obtained which is caused by performance of the reagent, any variation between lots of reagent, or protocol changes by the manufacturer.

SHIPPING DAMAGE

If damaged product is received, notify your Beckman Coulter Clinical Support Center.

* Synchron CX, Synchron LX and UniCel Dx_C are registered trademark of Beckman Coulter Inc., Fullerton, CA 92835