DRI® Tricyclics Serum Tox Assay Application – BECKMAN COULTER* UniCel* DxC and Synchron* Systems

Beckman Coulter Reorder Number A53705

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

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® Tricyclics Serum Tox Assay Kit Sales Group (1 X 25 mL / 1 X 8 mL, Important Note)	A53705
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.

Reagent Storage

Please refer to the reagent package 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® Tricyclics 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, calibration shall be performed every 14 days or as indicated by control recovery.
To monitor semi-quantitatively, calibration shall be performed every 7 days on Synchron CX and 14 days on Synchron LX/UniCel DxC or as indicated by control recovery.

Application Parameters

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

Number **[*]** Chem **[STCX]** **<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	**[300.0]**	5	**[ ]**	
	3	**[1000.0]**	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		**[7] 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 Tricyclics Serum Tox Assay chemistry parameters for **qualitative** mode on the SYNCHRON CX analyzer.

Number **[*]** Chem **[STCX]** **<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	**[300.0]**	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	**[7] 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 Tricyclics Serum Tox Assay chemistry parameters for **semi-quantitative** mode on the UniCel DxC and SYNCHRON LX analyzers.

Number **[*]** Chem **[STCX]** **<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 **[500.0]**
	2	**[150.0]**	5 **[1000.0]**
	3	**[300.0]**	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		**[7] 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	**[0.011]** **[0.004]**
		[0.010] **[0.031]**
		[0.006] **[ ]**
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 Tricyclics Serum Tox Assay chemistry parameters for **semi-quantitative** mode on the SYNCHRON CX analyzer.

Number **[*]** Chem **[STCX]** **<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	**[500.0]**
	2	**[150.0]**	5	**[1000.0]**
	3	**[300.0]**	6	**[ ]**
Cal Time Limit		**[168] 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	**[7] 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	**[0.008]**	**4-5**	**[0.006]**
	2-3	**[0.010]**	**5-1**	**[0.029]**
	3-4	**[0.006]**		**[ ]**

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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
Serum Sensitivity	**24.3 ng/mL**	**22.9 ng/mL**	**13.1 ng/mL**

Typical Precision

Instrument operated and maintained according to the manufacturer's instructions should exhibit a Qualitative within-run coefficient of variation of ≤ 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 (150 ng/mL)	179.4	2.56	**1.43**	186.5	1.50	**0.80**	189.3	2.35	**1.24**
Cutoff Calibrator (300 ng/mL)	207.2	2.48	**1.20**	215.6	1.66	**0.77**	217.9	2.21	**1.01**
Serum Tox Cal 3 (500 ng/mL)	247.2	1.83	**0.74**	256.0	1.35	**0.53**	256.7	1.65	**0.64**

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 (150 ng/mL)	179.4	3.13	**1.74**	186.5	1.82	**0.98**	189.3	3.03	**1.60**
Cutoff Calibrator (300 ng/mL)	207.2	2.99	**1.44**	215.6	1.88	**0.87**	217.9	2.73	**1.25**
Serum Tox Cal 3 (500 ng/mL)	247.2	2.59	**1.05**	256.0	1.57	**0.61**	256.7	1.75	**0.68**

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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 (150 ng/mL)	174.6	4.24	**2.43**	171.8	4.21	**2.45**	172.7	7.09	**4.10**
Cutoff Calibrator (300 ng/mL)	291.0	5.66	**1.95**	289.9	8.21	**2.83**	291.5	12.24	**4.20**
Serum Tox Cal 3 (500 ng/mL)	585.7	16.86	**2.88**	597.4	21.25	**3.56**	576.6	23.38	**4.05**

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 (150 ng/mL)	174.6	7.93	**4.54**	171.8	4.78	**2.78**	172.7	10.97	**6.35**
Cutoff Calibrator (300 ng/mL)	291.0	10.42	**3.58**	289.8	10.51	**3.63**	291.5	17.40	**5.97**
Serum Tox Cal 3 (500 ng/mL)	585.7	23.07	**3.94**	597.4	27.11	**4.54**	576.6	29.61	**5.13**

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Cross Reactivity

The following tricyclic antidepressants 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 tricyclics.

Cross-Reactant	Tested Concentration (ng/mL)
Cutoff Calibrator Nortriptyline	**300**
Amitriptyline	400
Amoxapine	100000
Chlorpromazine	1300
Clomipramine	350
Cyclobenzaprine	400
Desipramine	250
Doxepin	550
Imipramine	350
Protriptyline	450
Trimipramine	1000

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Results and Data Interpretation, continued

Method Comparison

A total of 154 serum samples and 129 urine 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 the concordance studies are presented in the tables below.

Qualitative-serum:

		CX +	CX -
H717	+	80	2
	-	6	66
Positive Sample Agreement		98%	
Negative Sample Agreement		92%	
Total Sample Agreement		95%	

		DxC +	DxC -
H717	+	81	1
	-	4	68
Positive Sample Agreement:		99%	
Negative Sample Agreement		94%	
Total Sample Agreement		97%	

		LX +	LX -
H717	+	80	2
	-	5	67
Positive Sample Agreement:		98%	
Negative Sample Agreement		93%	
Total Sample Agreement		95%	

Semi-quantitative-serum:

		CX +	CX -
H717	+	76	0
	-	6	71
Positive Sample Agreement		100%	
Negative Sample Agreement		92%	
Total Sample Agreement		96%	

		DxC +	DxC -
H717	+	76	0
	-	5	72
Positive Sample Agreement:		100%	
Negative Sample Agreement		94%	
Total Sample Agreement		97%	

		LX +	LX -
H717	+	76	0
	-	3	74
Positive Sample Agreement:		100%	
Negative Sample Agreement		96%	
Total Sample Agreement		98%	

Note: 14 samples out of total 154 samples exhibited non-concordance between reference method and one or more Synchron instruments, by either qualitative or semi-quantitative analysis. All non-concordant samples had tricyclics concentrations close to (within ±25%) the cutoff level of 300 ng/mL.

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Results and Data Interpretation, continued

Qualitative-urine:

		CX	
		+	-
H717	+	64	0
	-	4	61
Positive Sample Agreement			100%
Negative Sample Agreement			94%
Total Sample Agreement			97%

		DxC	
		+	-
H717	+	64	0
	-	5	60
Positive Sample Agreement:			100%
Negative Sample Agreement			92%
Total Sample Agreement			96%

		LX	
		+	-
H717	+	64	0
	-	5	60
Positive Sample Agreement:			100%
Negative Sample Agreement			92%
Total Sample Agreement			96%

Semi-quantitative-urine:

		CX	
		+	-
H717	+	62	1
	-	2	64
Positive Sample Agreement			98%
Negative Sample Agreement			97%
Total Sample Agreement			98%

		DxC	
		+	-
H717	+	62	1
	-	2	64
Positive Sample Agreement:			98%
Negative Sample Agreement			97%
Total Sample Agreement			98%

		LX	
		+	-
H717	+	63	0
	-	3	63
Positive Sample Agreement:			100%
Negative Sample Agreement			95%
Total Sample Agreement			98%

Note: 7 samples out of total 129 samples exhibited non-concordance between reference method and one or more Synchron instruments, by either qualitative or semi-quantitative analysis. All non-concordant samples had tricyclics concentrations close to (within ±25%) the cutoff level of 300 ng/mL.

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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* DxC, 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 DxC 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.

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