Microgenics Corporation
Part of Thermo Fisher Scientific

DRI® ETHYL GLUCURONIDE APPLICATION BECKMAN COULTER DxC 700 AU®

CE

Beckman Coulter Reagent REF E0750310

Intended for the qualitative and semi-quantitative determination of Ethyl Glucuronide in human urine at cutoffs of 500 ng/mL and 1000 ng/mL. This application pertains only to the 500 ng/mL cutoff.

IVD For In Vitro Diagnostic Use Only
For Export Only, Not Available in the United States
Rx Only

Purpose

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

Item	Size	Beckman Coulter Reorder Number
DRI Ethyl Glucuronide Assay	1 x 18 mL	E0750310
DRI Ethyl Glucuronide Negative Calibrator	1 x 25 mL	E0750311
DRI Ethyl Glucuronide 100 Calibrator	1 x 10 mL	E0750312
DRI Ethyl Glucuronide 500 Calibrator	1 x 10 mL	E0750313
DRI Ethyl Glucuronide 1000 Calibrator	1 x 10 mL	E0750314
DRI Ethyl Glucuronide 2000 Calibrator	1 x 10 mL	E0750315
DRI Ethyl Glucuronide 375 Control	1 x 25 mL	E0750316
DRI Ethyl Glucuronide 625 Control	1 x 25 mL	E0750317
AU Bottle	20 X 30 mL	63094

Technical Support

For Technical Support, please contact your local Beckman Coulter Representative.

Reagent Storage

Refer to the package insert for information on reagent storage.

Continued on next page

Clinical Diagnostics
Microgenics Corporation
46500 Kato Road
Fremont, CA USA
94538
510-979-5000
510-979-5420 fax
www.thermofisher.com
Toll Free: 800-232-3342

Instructions For Use

Procedure for Analyzer

Refer to the operator's manuals for information on analyzer operation. Refer to the package insert for complete reagent preparation.

Prior to pouring into AU bottles, allow the reagent to equilibrate for 15 minutes at refrigerated temperature (2 to 8ºC). Dispense R1 reagent and R2 reagent into appropriate AU bottles as shown in the table below:

	AU Reagent Bottle	
DRI Ethyl Glucuronide Assay Kit	R1 Compartment	R2 Compartment
Antibody/Substrate Reagent R1	One Bottle (30 mL)	
Enzyme Conjugate Reagent R2		One Bottle (30 mL)

Warning: These reagents have to be programmed to fixed positions. Do not use the Thermo reagent bottles directly on the AU analyzer.

Results and Data Interpretation

Results for samples will be printed in ng/mL.

Specimen Preparation

Refer to the package insert for the complete specimen preparation. The product insert can be found at the Thermo Fisher Scientific website:

www.thermofisher.com

Calibration

Use the DRI Ethyl Glucuronide calibrators. The calibrators are liquid and ready-to-use.

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DRI Ethyl Glucuronide Assay
Beckman Coulter System Parameters, DxC 700 AU - Qualitative

General	LIH	ISE	Calculated Test	Range

Test Name: # ▼ **Type:** Urine ▼ **Operation** Yes ▼

Sample Volume		25.0 µL	Dilution	0 ▼ µL	OD Limit					
Pre-Dilution Rate		1 ▼					Min. OD	-2.0000	Max OD	3.0000
Reagent Volume	R1 (R1-1)	57 µL	Dilution	0 µL	Reagent OD Limit 1st		Low	-2.0000	High	3.0000
	R1-2	µL	Dilution	µL	Last		Low	-2.0000	High	3.0000
	R2 (R2-1)	57 µL	Dilution	0 µL	Analytical Measuring Range		Low	-9999	High	9999
Common Reagent	Type	None	Name	None	Correlation Factor		A	1	B	0
Wavelength	Pri	340 ▼ nm	Sec	410 ▼ nm	Manufacturer Factor		A	1	B	0
Method		FIXED ▼								
Reaction Slope		+ ▼			Onboard Stability Period		30	Day	0	Hour
Measuring Point-1	1st	13	Last	17	LIH Influence Check		No ▼			
Measuring Point-2	1st		Last		Lipemia		+ ▼			
Linearity Limit		%			Icterus		+ ▼			
Lag Time Check		No ▼			Hemolysis		+ ▼			

General	LIH	ISE	Calculated Test	Range

Test Name: # ▼ **Type:** Urine ▼

Value/Flag: Flag — Level: Low -999999, High 500

Specific Ranges

	Sex	From Year	From Month	To Year	To Month	Other Type	Low	High
☐ 1:	# ▼	#	#	#	#	None	#	#
☐ 2:	# ▼	#	#	#	#	None	#	#
☐ 3:	# ▼	#	#	#	#	None	#	#
☐ 4	# ▼	#	#	#	#	None	#	#
☐ 5:	# ▼	#	#	#	#	None	#	#
☐ 6:	# ▼	#	#	#	#	None	#	#
7:	Standard demographics						#	#
8:	Not within expected values						#	#

Critical Limits: Low # — High # — Unit ng/mL — Select — Decimal Places 0

User-defined

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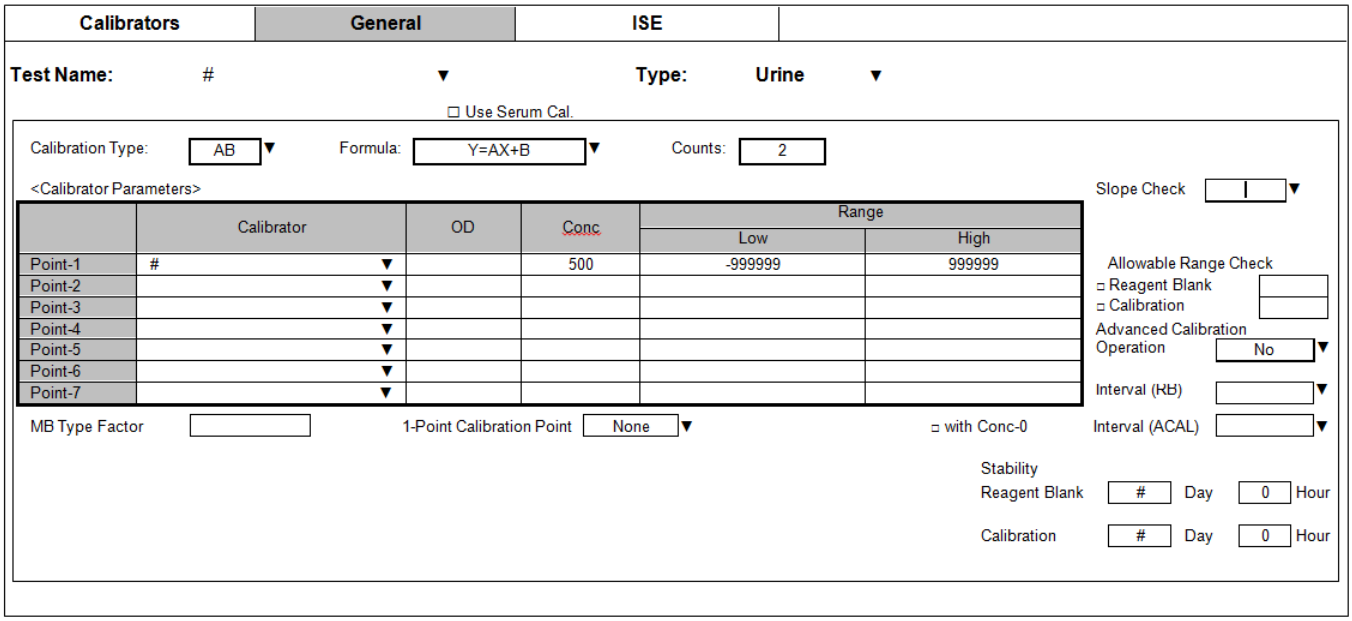
DRI Ethyl Glucuronide Assay
Beckman Coulter System Parameters, DxC 700 AU – Qualitative, *continued*



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DRI Ethyl Glucuronide Assay
Beckman Coulter System Parameters, DxC 700 AU – Semiquantitative

General	LIH	ISE	Calculated Test	Range

Test Name: # ▼ **Type:** Urine ▼ **Operation** Yes ▼

Sample Volume		25.0 µL	Dilution	0 ▼ µL	OD Limit				
Pre-Dilution Rate		1 ▼					Min. OD	-2.0000	Max OD 3.0000
					Reagent OD Limit				
Reagent Volume	R1 (R1-1)	57 µL	Dilution	0 µL	1st		Low	-2.0000	High 3.0000
	R1-2	µL	Dilution	µL	Last		Low	-2.0000	High 3.0000
	R2 (R2-1)	57 µL	Dilution	0 µL	Analytical Measuring Range		Low	-9999	High 9999
Common Reagent	Type	None	Name	None	Correlation Factor		A	1	B 0
Wavelength	Pri	340 ▼ nm	Sec	410 ▼ nm	Manufacturer Factor		A	1	B 0
Method		FIXED1 ▼							
Reaction Slope		+ ▼			Onboard Stability Period		30 Day	0 Hour	
Measuring Point-1	1st	13	Last	17	LIH Influence Check		No ▼		
Measuring Point-2	1st		Last		Lipemia		+ ▼		
Linearity Limit		%			Icterus		+ ▼		
Lag Time Check		No ▼			Hemolysis		+ ▼		

General	LIH	ISE	Calculated Test	Range

Test Name: # ▼ **Type:** Urine ▼

Value/Flag: Value — Level: Low -999999 High 500

Specific Ranges

	Sex	From Year	From Month	To Year	To Month	Other Type	Low	High
☐ 1:	# ▼	#	#	#	#	None	#	#
☐ 2:	# ▼	#	#	#	#	None	#	#
☐ 3:	# ▼	#	#	#	#	None	#	#
☐ 4	# ▼	#	#	#	#	None	#	#
☐ 5:	# ▼	#	#	#	#	None	#	#
☐ 6:	# ▼	#	#	#	#	None	#	#
7:	Standard demographics						#	#
8:	Not within expected values						#	#

Critical Limits: Low # High # Unit ng/mL Select Decimal Places 1

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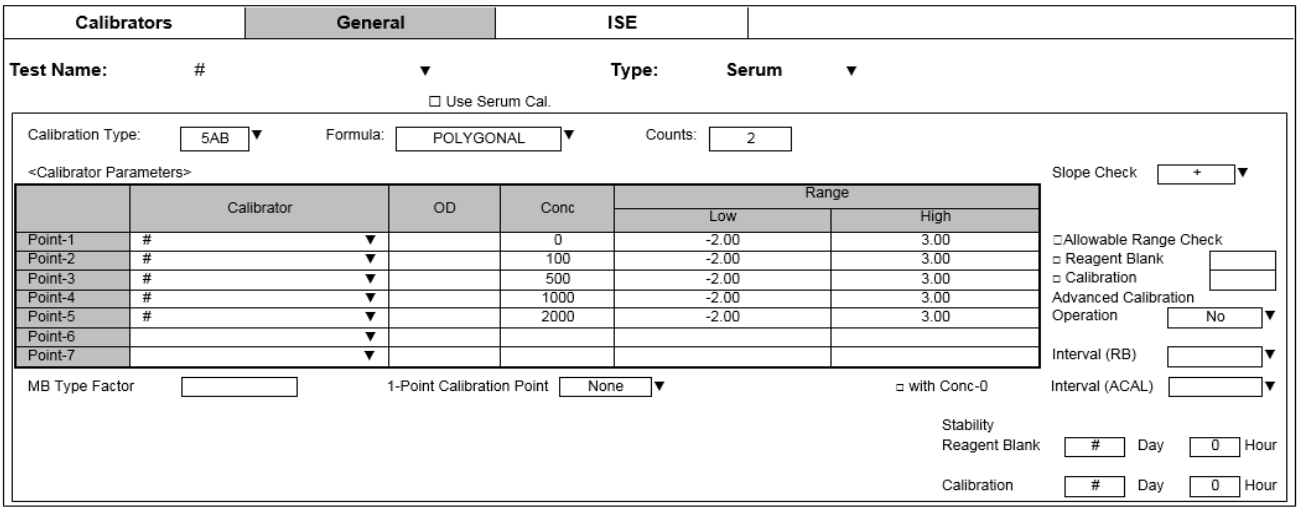

Calibrators | General | ISE

Test Name: # ▼ Type: Serum ▼

☐ 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	# ▼		100	-2.00	3.00
Point-3	# ▼		500	-2.00	3.00
Point-4	# ▼		1000	-2.00	3.00
Point-5	# ▼		2000	-2.00	3.00
Point-6	▼				
Point-7	▼				

Slope Check + ▼

☐Allowable Range Check
☐ Reagent Blank
☐ Calibration
Advanced Calibration Operation No ▼
Interval (RB) ▼
Interval (ACAL) ▼

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

Stability
Reagent Blank # Day 0 Hour
Calibration # Day 0 Hour

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Additional Information

Important

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

Please notify your Beckman Coulter Technical Support Center if this product is received damaged.

CE

EC REP B·R·A·H·M·S GmbH, Neuendorfstrasse 25, 16761 Hennigsdorf, Germany

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