

DRI[®] ETHYL GLUCURONIDE APPLICATION BECKMAN COULTER DxC 500 AU / 500i



Beckman Coulter Reagent REF E0750310

This Application is Intended for the Qualitative and Semiquantitative Determination of Ethyl Glucuronide in Human Urine at the cutoff of 500 ng/mL.



For In Vitro Diagnostic Use Only
Rx 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

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.

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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. 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 8°C). 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. Refer to the package insert for the concentration of each calibrator.

Reagent Name: DRI Ethyl Glucuronide Assay (Qualitative- 500 ng/mL Cutoff Only)
REF E0750310 DxC 500 AU / 500i Urine Settings
Calibrator Name: DRI Ethyl Glucuronide Calibrator REF E0750313

Reagent ID 558

TEST CONFIGURATION & CHEMISTRY DETAILS

Assay Name	Test	Rev	Discipline	Chemistry		
Test ID	ETG500		Calculated Result	☐		
LIS Code	ETG500		Result Type	Qualitative ▼		
UNITS AND RANGE SETTINGS						
Use Settings from	None ▼	Units	None ▼	Decimal Places	x ▼	Urine
Test Kind	General ▼	Revision	01	☒ Multi Reagent Switch		
Reagent Name	ETG	Reagent ID	558	☐ FSE Test		
ABB Name	ETG1N	Parameter Long Name	Ethyl Glucur 500 (Q) E0750310 ETG1N Urine			
Region	☐ US	☒ OUS	☒ AP	☐ JP	☒ EU	☐ Other

GENERAL PARAMETERS

SAMPLE VOLUME		REACTION OD LIMIT					
Sample Volume	25.0 µL	Low	-2.0000	High	3.0000		
Predilution Rate	1 ▼						
REAGENT VOLUME		REACTION BLANK OD LIMIT					
R1-1	57 µL	First: Low	-2.0000	High	3.0000		
R2-1	57 µL	Last: Low	-2.0000	High	3.0000		
		ANALYTICAL MEASURING RANGE					
		Low	100.00	High	2000.00		
WAVELENGTH		MANUFACTURER FACTOR					
Primary	340 nm	Secondary	410 nm	A	1	B	0
METHOD		REAGENT ONBOARD STABILITY					
FIXED ▼		31 Days				0 Hours	
REACTION SLOPE		LIH INFLUENCE CHECK					
+		☐ Perform LIH check					
MEASURING POINT		Lipemia				+	▼
Point 1: First	13	Last	17	Icterus	+	▼	
Point 2: First		Last		Hemolysis	+	▼	
Linearity Limit						%	
Lag Time Check		☐ Perform Lag Time Check					

Reagent Name: DRI Ethyl Glucuronide Assay (Qualitative- 500 ng/mL Cutoff Only)
REF E0750310 Dx C 500 AU / 500i Urine Settings
Calibrator Name: DRI Ethyl Glucuronide Calibrator REF E0750313, Continued

Reagent ID 558

CALIBRATION PARAMETERS

Base Unit	Decimal Place	Unit 1	Factor 1	Unit 2	Factor 2	Unit 3	Factor 3	Unit 4	Factor 4
None ▼	0	None ▼	0	None ▼	0	None ▼	0	None ▼	0

CALIBRATOR SPECIFIC

Calibration Type

Counts

Formula

MB Factor

Calibrator Name

Positive Cutoff

☐ SLOPE CHECK

Number of Levels

Slope Check

STABILITY AND INTERVAL

Reagent Blank Stability Days Hours

Calibration Stability Days Hours

Interval

Interval

CALIBRATION OD AND CONCENTRATION PARAMETERS

☐ Use highest calibrator for Upper AMR

	Calibrator Name	Conc	Factor Range Low	Factor Range High
Point 1	ETG CAL-3	500	-99999	99999
Point 2				
Point 3				
Point 4				
Point 5				
Point 6				
Point 7				

OD DELTA CHECK

☐ Reagent Blank

☐ Calibration

PROZONE CHECK PARAMETERS

☐ Logic Check 1

Check Points

Point 1
 Point 2
 Point 3

Decision Values

Value 1
 Value 2
 Value 3

☐ Logic Check 2

Check Points

Point 1
 Interval

Decision Values

Value 1
 Value 2

☐ Logic Check 3

Check Points

Point 1
 Interval

Decision Values

Value 1
 Value 2

Limit Points

Limit 1
 Limit 2

Limit Points

Limit 1
 Limit 2

Limit Points

Limit 1
 Limit 2

Check Pattern

Pattern

Reagent Name: DRI Ethyl Glucuronide Assay (Semi-Quantitative- 500 ng/mL Cutoff Only)
REF E0750310 Dx C 500 AU / 500i Urine Settings
Calibrator Name: DRI Ethyl Glucuronide Calibrators REF E0750311, E0750312, E0750313, E0750314, E0750315

Reagent ID 558

TEST CONFIGURATION & CHEMISTRY DETAILS

Assay Name	Test	Rev	Discipline	Chemistry		
Test ID	ETG500-		Calculated Result	☐		
LIS Code	ETG500-		Result Type	Semiquantitative ▼		
UNITS AND RANGE SETTINGS						
Use Settings from	None ▼	Units	ng/mL ▼	Decimal Places	x.xx ▼	Urine
Test Kind	General ▼	Revision	01	☒ Multi Reagent Switch		
Reagent Name	ETG	Reagent ID	558	☐ FSE Test		
ABB Name	ETG2N	Parameter Long Name	Ethyl Glucur S/Q E0750310 ETG2N Urine			
Region	☐ US	☒ OUS	☒ AP	☐ JP	☒ EU	☐ Other

GENERAL PARAMETERS

SAMPLE VOLUME	Sample Volume	25.0	μL	Dilution	0	μL	REACTION OD LIMIT	Low	-2.0000	High	3.0000	
	Predilution Rate	1					REACTION BLANK OD LIMIT	First: Low	-2.0000	High	3.0000	
REAGENT VOLUME	R1-1	57	μL	Dilution	0	μL		Last: Low	-2.0000	High	3.0000	
	R2-1	57	μL	Dilution	0	μL	ANALYTICAL MEASURING RANGE	Low	100.00	High	2000.00	
WAVELENGTH	Primary	340	nm	Secondary	410	nm	MANUFACTURER FACTOR	A	1	B	0	
METHOD	FIXED 1 ▼						REAGENT ONBOARD STABILITY		31	Days	0	Hours
REACTION SLOPE	+						LIH INFLUENCE CHECK	☐ Perform LIH check				
MEASURING POINT	Point 1: First	13		Last	17		Lipemia	+	▼			
	Point 2: First			Last			Icterus	+	▼			
							Hemolysis	+	▼			
Linearity Limit												
Lag Time Check	☐ Perform Lag Time Check											

Reagent Name: DRI Ethyl Glucuronide Assay (Semi-Quantitative- 500 ng/mL Cutoff Only)
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Reagent ID 558

CALIBRATION PARAMETERS

Base Unit	Decimal Place	Unit 1	Factor 1	Unit 2	Factor 2	Unit 3	Factor 3	Unit 4	Factor 4
ng/mL	2	None	0	None	0	None	0	None	0

CALIBRATOR SPECIFIC

Calibration Type

Counts

☐ Use highest calibrator for Upper AMR

Formula

MB Factor

Calibrator Name

Positive Cutoff

Add

☒ SLOPE CHECK

Number of Levels

Slope Check

STABILITY AND INTERVAL

Reagent Blank Stability

Days

Hours

Interval

Calibration Stability

Days

Hours

Interval

CALIBRATION OD AND CONCENTRATION PARAMETERS

	Calibrator Name	Conc	OD Range Low	OD Range High
Point 1	ETG CAL-1	0.00	-2.00	3.00
Point 2	ETG CAL-2	100.00	-2.00	3.00
Point 3	ETG CAL-3	500.00	-2.00	3.00
Point 4	ETG CAL-4	1000.00	-2.00	3.00
Point 5	ETG CAL-5	2000.00	-2.00	3.00
Point 6				
Point 7				

OD DELTA CHECK

☐ Reagent Blank

☐ Calibration

PROZONE CHECK PARAMETERS

☐ Logic Check 1

Check Points

Point 1	0
Point 2	0
Point 3	0

Decision Values

Value 1	0
Value 2	0
Value 3	0

☐ Logic Check 2

Check Points

Point 1	0
Interval	1

Decision Values

Value 1	0
Value 2	0

☐ Logic Check 3

Check Points

Point 1	0
Interval	1

Decision Values

Value 1	0
Value 2	0

Limit Points

Limit 1	0
Limit 2	27

Limit Points

Limit 1	0
Limit 2	27

Limit Points

Limit 1	0
Limit 2	27

Check Pattern

Pattern

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.

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