

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



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 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	<input type="text" value="ETG500"/>		Calculated Result	<input type="checkbox"/>
LIS Code	<input type="text" value="ETG500"/>		Result Type	<input type="text" value="Qualitative"/>

UNITS AND RANGE SETTINGS

Use Settings from	<input type="text" value="None"/>	Units	<input type="text" value="None"/>	Decimal Places	<input type="text" value="x"/>	<input type="text" value="Urine"/>
Test Kind	<input type="text" value="General"/>	Revision	<input type="text" value="01"/>	<input checked="" type="checkbox"/> Multi Reagent Switch		
Reagent Name	<input type="text" value="ETG"/>	Reagent ID	<input type="text" value="558"/>	<input type="checkbox"/> FSE Test		
ABB Name	<input type="text" value="ETG1N"/>	Parameter Long Name	<input type="text" value="Ethyl Glucur 500 (Q) E0750310 ETG1N Urine"/>			
Region	<input type="checkbox"/> US	<input checked="" type="checkbox"/> OUS	<input checked="" type="checkbox"/> AP	<input type="checkbox"/> JP	<input checked="" type="checkbox"/> EU	<input type="checkbox"/> Other

GENERAL PARAMETERS

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

Reagent Name: DRI Ethyl Glucuronide Assay (Qualitative- 500 ng/mL Cutoff Only)
REF E0750310 Dx C 500 AU 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

Add

SLOPE CHECK

Number of Levels

Slope Check

STABILITY AND INTERVAL

Reagent Blank Stability Days Hours
 Calibration Stability Days Hours

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

Limit Points
 Limit 1
 Limit 2

Check Pattern
 Pattern

Logic Check 2

Decision Values
 Value 1
 Value 2
 Value 3

Check Points
 Point 1
 Interval

Limit Points
 Limit 1
 Limit 2

Logic Check 3

Decision Values
 Value 1
 Value 2

Check Points
 Point 1
 Interval

Limit Points
 Limit 1
 Limit 2

Reagent Name: DRI Ethyl Glucuronide Assay (Semi-Quantitative- 500 ng/mL Cutoff Only)
REF E0750310 DxC 500 AU 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	<input type="checkbox"/>
LIS Code	ETG500-		Result Type	Semiquantitative ▼
UNITS AND RANGE SETTINGS				
Use Settings from	None ▼	Units	ng/mL ▼	Decimal Places
				x.xx ▼
Test Kind	General ▼	Revision	01	<input checked="" type="checkbox"/> Multi Reagent Switch
Reagent Name	ETG	Reagent ID	558	<input type="checkbox"/> FSE Test
ABB Name	ETG2N	Parameter Long Name	Ethyl Glucur S/Q E0750310 ETG2N Urine	
Region	<input type="checkbox"/> US	<input checked="" type="checkbox"/> OUS	<input checked="" type="checkbox"/> AP	<input type="checkbox"/> JP
			<input checked="" type="checkbox"/> EU	<input type="checkbox"/> 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
REACTION SLOPE	+								Hours
MEASURING POINT	Point 1: First	13	Last	17	LIH INFLUENCE CHECK	<input type="checkbox"/> Perform LIH check			
	Point 2: First		Last		Lipemia	+	▼		
Linearity Limit					Icterus	+	▼		
Lag Time Check	<input type="checkbox"/> Perform Lag Time Check				Hemolysis	+	▼		

Reagent Name: DRI Ethyl Glucuronide Assay (Semi-Quantitative- 500 ng/mL Cutoff Only)
 REF E0750310 DxC 500 AU Urine Settings
 Calibrator Name: DRI Ethyl Glucuronide Calibrators REF E0750311, E0750312, E0750313,
 E0750314, E0750315, *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
ng/mL	2	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

Interval

Calibration Stability Days Hours

Interval

CALIBRATION OD AND CONCENTRATION PARAMETERS

Use highest calibrator for Upper AMR

	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
 Point 2
 Point 3

Decision Values
 Value 1
 Value 2
 Value 3

Logic Check 2

Check Points
 Point 1
 Interval

Limit Points
 Limit 1
 Limit 2

Logic Check 3

Check Points
 Point 1
 Interval

Limit Points
 Limit 1
 Limit 2

Decision Values
 Value 1
 Value 2

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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