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# DRI® ETHYL GLUCURONIDE APPLICATION BECKMAN COULTER AU400®, AU480®, AU640®, AU680®, AU2700®, AU5400®, AU5800®

CE

Catalog No. 10011297, 10015626

**The Thermo Scientific™ DRI Ethyl Glucuronide Enzyme Immunoassay is intended for the qualitative and semiquantitative determination of ethyl glucuronide (EtG) in human urine at cutoffs of 500 ng/mL and 1000 ng/mL.**

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

## 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

Materials available from Microgenics, a part of Thermo Fisher Scientific:

| Item | Size | Catalog No. |
|---|---|---|
| DRI Ethyl Glucuronide Assay | 68 mL Kit<br>3 x 18 mL Kit | 10011297<br>10015626 |
| DRI Ethyl Glucuronide Negative Calibrator | 25 mL | 10011207 |
| DRI Ethyl Glucuronide 100 ng/mL Calibrator | 10 mL | 10011208 |
| DRI Ethyl Glucuronide 500 ng/mL Calibrator | 10 mL | 10011210 |
| DRI Ethyl Glucuronide 1000 ng/mL Calibrator | 10 mL | 10011212 |
| DRI Ethyl Glucuronide 2000 ng/mL Calibrator | 10 mL | 10011213 |
| DRI Ethyl Glucuronide 375 ng/mL Control | 25 mL | 10012135 |
| DRI Ethyl Glucuronide 625 ng/mL Control | 25 mL | 10012136 |
| DRI Ethyl Glucuronide 750 ng/mL Control | 25 mL | 10012137 |
| DRI Ethyl Glucuronide 1250 ng/mL Control | 25 mL | 10012138 |

To place an order or for technical service contact:

**Microgenics Corporation, part of Thermo Fisher Scientific**
**46500 Kato Road, Fremont, CA 94538 USA**
**U.S. Toll free: (800) 232-3342 / Tel: (510) 979-5000**
**U.S. Toll free fax: (888) 527-8001 / Fax: (510) 979-5420**

EC REP Microgenics GmbH, Spitalhofstrasse 94, D-94032 Passau, Germany

*Continued on next page*

## Reagent Storage

Refer to package insert for information on reagent storage.

## Procedure for Analyzer

Refer to operator's manuals for information on analyzer operation.

Dispense adequate amounts of Ab/Sub Reagent (first reagent) and Enz/Conjugate Reagent (second reagent) into appropriate containers. **Make sure that the reagents have equilibrated to the temperature of the analyzer reagent compartment before starting analysis.**

**Note**: Under Specific Test Parameters/General Tab, Linearity % should be left blank, as reflected in the following pages. **Do Not Enter 0.**

## Results and Data Interpretation

Results for samples will be printed in ng/mL for the semiquantitative assay and in % units for the qualitative assay.



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# DRI Ethyl Glucuronide – Qualitative
# Beckman Coulter System Parameters, AU400/AU640

**Specific Test Parameters**

General | LIH | ISE | Range

Test Name: ETGQ ∇ < > Type: Urine ∇ Operation: Yes ∇

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Sample: | Volume | 35.0 µL | Dilution | 0 µL | Pre-Dilution Rate: | 1 | | | |
| Reagents: | R1 Volume | 80 µL | Dilution | 0 µL | Min OD | | Max OD | | |
| | R2 Volume | 80 µL | Dilution | 0 µL | | L -2.00 | | H 2.50 | |
| | | | | | Reagent OD limit: | | | | |
| Wavelength: | Pri. | 340 ∇ | Sec. | 410 ∇ | | First L -2.00 | | First H 2.50 | |
| Method: | | RATE* ∇ | | | | Last L -2.00 | | Last H 2.50 | |
| Reaction slope: | | + ∇ | | | Dynamic Range: | | | | |
| Measuring Point 1: | First | 13 | Last | 17 | | L # | | H # | |
| Measuring Point 2: | First | | Last | | Correlation Factor: | | | | |
| Linearity | | % | | | | A 1 | | B 0 | |
| No-Lag-Time: | | No ∇ | | | On-board stability period: | # | | | |

**Specific Test Parameters**

General | LIH | ISE | Range

Test Name: ETGQ ∇ < > Type: Urine ∇

Value/Flag: # ∇ Level L: # Level H: #

Normal Ranges:

| | Sex | Age L Year | Age L Month | Age H Year | Age H Month | L | H |
|---|---|---|---|---|---|---|---|
| ☐ 1. | # ∇ | # | # | # | # | # | # |
| ☐ 2. | # ∇ | # | # | # | # | # | # |
| ☐ 3. | # ∇ | # | # | # | # | # | # |
| ☐ 4. | # ∇ | # | # | # | # | # | # |
| ☐ 5. | # ∇ | # | # | # | # | # | # |
| ☐ 6. | # ∇ | # | # | # | # | # | # |
| 7. None Selected | | | | | | # | # |
| 8. Out of Range | | L | | H | | # | # |

Panic Value: L # H # Unit: # Decimal places: #

**Calibration Specific**

General | ISE

Test Name: ETGQ ∇ < > Type Urine ∇

Calibration Type: AB ∇ Formula: Y=AX+B ∇ Counts: 2 Process: CONC ∇

| | Cal. No. | OD | CONC | Factor/OD-L | Factor/OD-H |
|---|---|---|---|---|---|
| Point 1: | # | | 100 | -99999 | 999999 |
| Point 2: | | | | | |
| Point 3: | | | | | |
| Point 4: | | | | | |
| Point 5: | | | | | |
| Point 6: | | | | | |
| Point 7: | | | | | |

1-Point Cal. Point: ☐ With CONC-0 Slope Check + ∇ Advanced Calibration: ∇

MB Type Factor: Calibration Stability Period: #

\# User defined
* Can also be run as FIXED



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## DRI Ethyl Glucuronide – Semiquantitative
## Beckman Coulter System Parameters, AU400/AU640

Specific Test Parameters

General | LIH | ISE | Range

Test Name: ETGSQ ∇ < > Type: Urine ∇ Operation: Yes ∇

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Sample: | Volume | 35.0 | µL | Dilution | 0 | µL | Pre-Dilution Rate: | 1 | |
| Reagents: | R1 Volume | 80 | µL | Dilution | 0 | µL | Min OD | | Max OD |
| | R2 Volume | 80 | µL | Dilution | 0 | µL | L -2.00 | | H 2.50 |
| | | | | | | | Reagent OD limit: | | |
| Wavelength: | Pri. | 340 ∇ | | Sec. | 410 ∇ | | First L -2.00 | First H | 2.50 |
| Method: | | RATE1* ∇ | | | | | Last L -2.00 | Last H | 2.50 |
| Reaction slope: | | + ∇ | | | | | Dynamic Range: | | |
| Measuring Point 1: | First | 13 | | Last | 17 | | L 0 | H | 2000 |
| Measuring Point 2: | First | | | Last | | | Correlation Factor: | | |
| Linearity: | | | % | | | | A 1 | B | 0 |
| No Lag Time: | | No ∇ | | | | | On-board stability period: | # | |

Specific Test Parameters

General | LIH | ISE | Range

Test Name: ETGSQ ∇ < > Type: Urine ∇

Value/Flag: # ∇ Level L: # Level H: #

Normal Ranges:

| | Sex | Age L Year | Age L Month | Age H Year | Age H Month | L | H |
|---|---|---|---|---|---|---|---|
| ☐ 1. | # ∇ | # | # | # | # | # | # |
| ☐ 2. | # ∇ | # | # | # | # | # | # |
| ☐ 3. | # ∇ | # | # | # | # | # | # |
| ☐ 4. | # ∇ | # | # | # | # | # | # |
| ☐ 5. | # ∇ | # | # | # | # | # | # |
| ☐ 6. | # ∇ | # | # | # | # | # | # |
| 7. None Selected | | | | | | # | # |
| 8. Out of Range | | L | | H | | # | # |

Panic Value: # # Unit: ng/mL Decimal places: #

Calibration Specific

General | ISE

Test Name: ETGSQ ∇ < > Type Urine ∇

Calibration Type: 5AB ∇ Formula: POLYGONAL ∇ Counts: 2 Process: CONC ∇

| | Cal. No. | OD | CONC | Factor/OD-L | Factor/OD-H |
|---|---|---|---|---|---|
| Point 1: | 1 | | 0.0 | -2.0 | 2.5 |
| Point 2: | 2 | | 100.0 | -2.0 | 2.5 |
| Point 3: | 3 | | 500.0 | -2.0 | 2.5 |
| Point 4: | 4 | | 1000.0 | -2.0 | 2.5 |
| Point 5: | 5 | | 2000.0 | -2.0 | 2.5 |
| Point 6: | | | | | |
| Point 7: | | | | | |

1-Point Cal. Point: ☐ With CONC-0

MB Type Factor: Calibration Stability Period: #

# User defined

* Can also be run as FIXED1



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## DRI Ethyl Glucuronide – Qualitative
## Beckman Coulter System Parameters, AU2700/AU5400

Specific Test Parameters

General | LIH | ISE | Range

Test Name: ETGQ ▽ < > Type: Urine ▽ Operation: Yes ▽

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Sample: | Volume | 25.0 | µL | Dilution | 0 | µL | Pre-Dilution Rate: | 1 | |
| Reagents: | R1 Volume | 57 | µL | Dilution | 0 | µL | Min OD | | Max OD |
| | R2 Volume | 57 | µL | Dilution | 0 | µL | L -2.00 | | H 3.00 |
| | | | | | | | Reagent OD limit: | | |
| Wavelength: | Pri. | 340 ▽ | | Sec. | 410 ▽ | | First L -2.00 | | First H 3.00 |
| Method: | | FIXED* ▽ | | | | | Last L -2.00 | | Last H 3.00 |
| Reaction slope: | | + ▽ | | | | | Dynamic Range: | | |
| Measuring Point 1: | First | 13 | | Last | 17 | | L # | | H # |
| Measuring Point 2: | First | | | Last | | | Correlation Factor: | | |
| Linearity | | | % | | | | A 1 | | B 0 |
| No-Lag-Time: | | No ▽ | | | | | On-board stability period: # | | |

Specific Test Parameters

General | LIH | ISE | Range

Test Name: ETGQ ▽ < > Type: Urine ▽

Value/Flag: # ▽ Level L: # Level H: #

Normal Ranges:

| | Sex | Age L Year | Age L Month | Age H Year | Age H Month | L | H |
|---|---|---|---|---|---|---|---|
| ☐ 1. | # ▽ | # | # | # | # | # | # |
| ☐ 2. | # ▽ | # | # | # | # | # | # |
| ☐ 3. | # ▽ | # | # | # | # | # | # |
| ☐ 4. | # ▽ | # | # | # | # | # | # |
| ☐ 5. | # ▽ | # | # | # | # | # | # |
| ☐ 6. | # ▽ | # | # | # | # | # | # |
| 7. None Selected | | | | | | # | # |
| 8. Out of Range | | L | | H | | # | # |

Panic Value: # # Unit: # Decimal places: #

Calibration Specific

General ISE

Test Name: ETGQ ▽ < > Type Urine ▽

Calibration Type: AB ▽ Formula: Y=AX+B ▽ Counts: 2 Process: CONC ▽

| | Cal. No. | OD | CONC | Factor/OD-L | Factor/OD-H |
|---|---|---|---|---|---|
| Point 1: | # | | 100 | -99999 | 999999 |
| Point 2: | | | | | |
| Point 3: | | | | | |
| Point 4: | | | | | |
| Point 5: | | | | | |
| Point 6: | | | | | |
| Point 7: | | | | | |

1-Point Cal. Point: ☐ With CONC-0 Slope Check + ▽ Advanced Calibration: ▽

MB Type Factor: Calibration Stability Period: #

\# User defined
* Can also be run as FIXED



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## DRI Ethyl Glucuronide – Semiquantitative
## Beckman Coulter System Parameters, AU2700/AU5400

Specific Test Parameters

General | LIH | ISE | Range

Test Name: ETGSQ ∇ < > Type: Urine ∇ Operation: Yes ∇

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Sample: | Volume | 25.0 | µL | Dilution | 0 | µL | Pre-Dilution Rate: | 1 | |
| Reagents: | R1 Volume | 57 | µL | Dilution | 0 | µL | Min OD | | Max OD |
| | R2 Volume | 57 | µL | Dilution | 0 | µL | L -2.00 | | H 2.50 |
| | | | | | | | Reagent OD limit: | | |
| Wavelength: | Pri. | 340 ∇ | | Sec. | 410 ∇ | | First L -2.00 | | First H 2.50 |
| Method: | | RATE1* ∇ | | | | | Last L -2.00 | | Last H 2.50 |
| Reaction slope: | | + ∇ | | | | | Dynamic Range: | | |
| Measuring Point 1: | First | 13 | | Last | 17 | | L 0 | | H 2000 |
| Measuring Point 2: | First | | | Last | | | Correlation Factor: | | |
| Linearity: | | | % | | | | A 1 | | B 0 |
| No Lag Time: | | No ∇ | | | | | On-board stability period: | # | |

Specific Test Parameters

General | LIH | ISE | Range

Test Name: ETGSQ ∇ < > Type: Urine ∇

Value/Flag: # ∇ Level L: # Level H: #

Normal Ranges:

| | Sex | Age L Year | Age L Month | Age H Year | Age H Month | L | H |
|---|---|---|---|---|---|---|---|
| ☐ 1. | # ∇ | # | # | # | # | # | # |
| ☐ 2. | # ∇ | # | # | # | # | # | # |
| ☐ 3. | # ∇ | # | # | # | # | # | # |
| ☐ 4. | # ∇ | # | # | # | # | # | # |
| ☐ 5. | # ∇ | # | # | # | # | # | # |
| ☐ 6. | # ∇ | # | # | # | # | # | # |
| 7. None Selected | | | | | | # | # |
| 8. Out of Range | | L | | H | | # | # |

Panic Value: # # Unit: ng/mL Decimal places: #

Calibration Specific

General | ISE

Test Name: ETGSQ ∇ < > Type Urine ∇

Calibration Type: 5AB ∇ Formula: POLYGONAL ∇ Counts: 2 Process: CONC ∇

| | Cal. No. | OD | CONC | Factor/OD-L | Factor/OD-H |
|---|---|---|---|---|---|
| Point 1: | 1 | | 0.0 | -2.0 | 2.5 |
| Point 2: | 2 | | 100.0 | -2.0 | 2.5 |
| Point 3: | 3 | | 500.0 | -2.0 | 2.5 |
| Point 4: | 4 | | 1000.0 | -2.0 | 2.5 |
| Point 5: | 5 | | 2000.0 | -2.0 | 2.5 |
| Point 6: | | | | | |
| Point 7: | | | | | |

1-Point Cal. Point: ☐ With CONC-0

MB Type Factor: Calibration Stability Period: #

# User defined

* Can also be run as FIXED1



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# DRI Ethyl Glucuronide Assay – Qualitative
# Beckman Coulter System Parameters, AU480 / AU680

Specific Test Parameters

General | LIH | ISE | Range

Test Name: ETGQ ▽ < > Type: Urine ▽ Operation: Yes ▽

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Sample Volume | 25.0 µL | Dilution | 0 µL | OD Limit | | | |
| Pre-Dilution Rate | 1 | | | Min. OD | -2.00 | Max. OD | 3.00 |
| Reagents Volume: R1(R1-1) | 57 µL | Dilution | 0 µL | Reagent OD limit: | | | |
| | | | | First Low | -2.00 | High | 3.00 |
| | | | | Last Low | -2.00 | High | 3.00 |
| R2 (R2-1) | 57 µL | Dilution | 0 µL | | | | |
| | | | | Dynamic Range Low | # | High | # |
| | | | | Correlation Factor A | 1 | B | 0 |
| Wavelength: Pri. | 340 nm | Sec. | 410 nm | Factor for Maker A | 1 | B | 0 |
| Method: | FIXED* ▽ | | | | | | |
| Reaction slope: | + ▽ | | | Onboard Stability | 30 Days | 0 | Hour |
| Measuring Point 1: First | 13 | Last | 17 | LIH Influence Check | # ▽ | | |
| Measuring Point 2: First | | Last | | Lipemia | ▽ | | |
| Linearity: | % | | | Icterus | ▽ | | |
| No Lag Time: | No ▽ | | | Hemolysis | ▽ | | |

Specific Test Parameters

General | | ISE | Range

Test Name: ETGQ ▽ < > Type: Urine ▽

Value/Flag: # ▽ Level L: # Level H: #

Specific Ranges:

| | Sex | From Year | From Month | To Year | To Month | Low | High |
|---|---|---|---|---|---|---|---|
| ☐ 1. | # ▽ | # | # | # | # | # | # |
| ☐ 2. | # ▽ | # | # | # | # | # | # |
| ☐ 3. | # ▽ | # | # | # | # | # | # |
| ☐ 4. | # ▽ | # | # | # | # | # | # |
| ☐ 5. | # ▽ | # | # | # | # | # | # |
| ☐ 6. | # ▽ | # | # | # | # | # | # |
| 7. No demographics | | | | | | # | # |
| 8. Not within expected values | | | | | | # | # |

Panic Value: Low # High #

Unit # Decimal Places #

Calibration Specific

General | ISE

Test Name: ETGQ ▽ < > Type Urine ▽ ☐ Use Serum Cal.

Calibration Type: AB ▽ Formula: Y=AX+B ▽ Counts: 2

<Calibrator Parameters> Slope Check + ▽

| | Calibrator † | OD | Conc | Factor Range Low | Factor Range High |
|---|---|---|---|---|---|
| Point 1: | # ▽ | | 100 | -99999 | 999999 |
| Point 2: | ▽ | | | | |
| Point 3: | ▽ | | | | |
| Point 4: | ▽ | | | | |
| Point 5: | ▽ | | | | |
| Point 6: | ▽ | | | | |
| Point 7: | ▽ | | | | |
| Point 8: | ▽ | | | | |
| Point 9: | ▽ | | | | |
| Point10: | ▽ | | | | |

Allowable Range Check: ☐ Reagent Blank ☐ Calibration

Advanced Calibration: Operation No ▽ Interval (RB/ACAL) ▽

<Point Cal. For Master Curve> No. of Correction Points ▽ Use Master Curve ▽ ☐ Lot Calibration

| | Calibrator | OD | Conc | OD Range Low | OD Range High |
|---|---|---|---|---|---|
| Point 1: | | | | | |
| Point 2: | | | | | |

Stability: Reagent Blanks # Day # Hour; Calibration 30 Day 0 Hour

MB Type Factor: 1-Point Calibration Point ▽ ☐ With CONC-0

# User defined.

*Can also be run as RATE



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# DRI Ethyl Glucuronide Assay – Semiquantitative
# Beckman Coulter System Parameters, AU480 /AU680

**Specific Test Parameters**

General | LIH | ISE | Range

Test Name: ETGSQ ∇ < > Type: Urine ∇ Operation: Yes ∇

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Sample Volume | | 25.0 µL | Dilution | 0 µL | OD Limit | | |
| Pre-Dilution Rate | | 1 | | | Min. OD | -2.00 | Max. OD 3.00 |
| Reagents Volume: | R1(R1-1) | 57 µL | Dilution | 0 µL | Reagent OD limit: | | |
| | | | | | First Low | -2.00 | Hig 3.00 |
| | | | | | Last Low | -2.00 | Hig 3.00 |
| | R2 (R2-1) | 57 µL | Dilution | 0 µL | | | |
| | | | | | Dynamic Range Low | 0 | Hig 2000 |
| | | | | | Correlation Factor A | 1 | B 0 |
| Wavelength: | Pri. | 340 nm | Sec. | 410 nm | Factor for Maker A | 1 | B 0 |
| Method: | | FIXED1 ∇ | | | | | |
| Reaction slope: | | + ∇ | | | Onboard Stability | 30 Days | 0 Hour |
| Measuring Point 1: | First | 13 | Last | 17 | LIH Influence Check | # ∇ | |
| Measuring Point 2: | First | | Last | | Lipemia | ∇ | |
| Linearity: | | % | | | Icterus | ∇ | |
| No Lag Time: | | No ∇ | | | Hemolysis | ∇ | |

**Specific Test Parameters**

General | | ISE | Range

Test Name: ETGSQ ∇ < > Type: Urine ∇

Value/Flag: VALUE ∇ Level L: # Level H: #

Specific Ranges:

| | Sex | From Year | From Month | To Year | To Month | Low | High |
|---|---|---|---|---|---|---|---|
| ☐ 1. | # ∇ | # | # | # | # | # | # |
| ☐ 2. | # ∇ | # | # | # | # | # | # |
| ☐ 3. | # ∇ | # | # | # | # | # | # |
| ☐ 4. | # ∇ | # | # | # | # | # | # |
| ☐ 5. | # ∇ | # | # | # | # | # | # |
| ☐ 6. | # ∇ | # | # | # | # | # | # |
| 7. No demographics | | | | | | # | # |
| 8. Not within expected values | | | | | | # | # |

Panic Value

| Low | High |
|---|---|
| # | # |

Unit ng/mL Decimal Places #

**Calibration Specific**

General | ISE

Test Name: ETGSQ ∇ < > Type Urine ∇ ☐ Use Serum Cal.

Calibration Type: 5AB ∇ Formula: Polygonal ∇ Counts: 2

<Calibrator Parameters> Slope Check + ∇

| | Calibrator † | OD | Conc | Factor Range Low | Factor Range High |
|---|---|---|---|---|---|
| Point 1: | # ∇ | | 0.0 | -2.00 | 3.00 |
| Point 2: | # ∇ | | 100.0 | -2.00 | 3.00 |
| Point 3: | # ∇ | | 500.0 | -2.00 | 3.00 |
| Point 4: | # ∇ | | 1000.0 | -2.00 | 3.00 |
| Point 5: | # ∇ | | 2000.0 | -2.00 | 3.00 |
| Point 6: | ∇ | | | | |
| Point 7: | ∇ | | | | |
| Point 8: | ∇ | | | | |
| Point 9: | ∇ | | | | |
| Point10: | ∇ | | | | |

Allowable Range Check
☐ Reagent Blank
☐ Calibration

Advanced Calibration
Operation No ∇
Interval (RB/ACAL) ∇

<Point Cal. For Master Curve> No. of Correction Points ∇ Use Master Curve ∇ ☐ Lot Calibration

| | Calibrator | OD | Conc | OD Range Low | OD Range High |
|---|---|---|---|---|---|
| Point 1: | | | | | |
| Point 2: | | | | | |

Stability
Reagent Blanks # Day # Hour
Calibration 30 Day 0 Hour

MB Type Factor: 1-Point Calibration Point None ∇ ☐ With CONC-0

\# User Defined

* Can also be run as RATE1



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# DRI Ethyl Glucuronide Assay – Qualitative
# Beckman Coulter System Parameters, AU5800

Parameters | Specific Test Parameters
General | LIH | ISE | HbA1c | Calculated Test | Range

Test Name: ETGQ ▽ < > Type: Urine ▽ Operation Yes ▽

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Sample Volume | | 17.0 µL | Dilution | 0 µL | OD Limit | | | | |
| Pre-Dilution Rate | | 1 ▽ | Diluent Bottle | Outside ▽ | Min.OD | -2.00 | Max.OD | 3.00 | |
| Rgt. Volume | R1(R1-1) | 39 µL | Dilution | 0 µL | Reagent OD Limit | | | | |
| | R1-2 | µL | Dilution | µL | 1st. | Low | -2.00 | High | 3.00 |
| | | | | | Last | Low | -2.00 | High | 3.00 |
| | R2(R2-1) | 39 µL | Dilution | 0 µL | | | | | |
| | | | | | Dynamic Range | Low | # | High | # |
| Common Rgt. Type | | None | Name | None | Correlation Factor | A | 1 | B | 0 |
| Wavelength | Pri | 340 ▽nm | Sec. | 410 ▽nm | Factor for Maker | A | 1 | B | 0 |
| Method | | FIXED* ▽ | | | | | | | |
| Reaction Slope | | + ▽ | | | Onboard Stability Period | | 30 Day | 0 Hour | |
| Measuring Point1 1st | | 13 | Last | 17 | LIH Influence Check | | No ▽ | | |
| Measuring Point2 1st | | | Last | | Lipemia | | ▽ | | |
| Linearity Limit | | % | | | Icterus | | ▽ | | |
| Lag Time Check | | No ▽ | | | Hemolysis | | ▽ | | |

Parameters | Specific Test Parameters
General | LIH | ISE | HbA1c | Calculated Test | Range

Test Name: ETGQ ▽ < > Type: Urine ▽

Value/Flag: # ▽

Level Low # High #

Specific Ranges:

| | Sex | From Year | From Month | To Year | To Month | Low | High |
|---|---|---|---|---|---|---|---|
| ☐ 1. | # ▽ | # | # | # | # | # | # |
| ☐ 2. | # ▽ | # | # | # | # | # | # |
| ☐ 3. | # ▽ | # | # | # | # | # | # |
| ☐ 4. | # ▽ | # | # | # | # | # | # |
| ☐ 5. | # ▽ | # | # | # | # | # | # |
| ☐ 6. | # ▽ | # | # | # | # | # | # |
| 7. Standard demographics | | | | | | # | # |
| 8. Not within expected values | | | | | | # | # |

Panic Value Low # High # Unit # Decimal Places #

Parameters | Calibration Parameters
Calibrators | Calibration Specific
General | ISE

Test Name: ETGQ ▽ < > Type Urine ▽ Cuvette . ▽

☐ Use Serum Cal.

Calibration Type: AB ▽ Formula: Y=AX+B ▽ Counts: 2 ▽

<Calibrator Parameters>

| | Calibrator | OD | Conc | Range Low | Range High |
|---|---|---|---|---|---|
| Point 1: | # ▽ | | 100 | -99999 | 999999 |
| Point 2: | ▽ | | | | |
| Point 3: | ▽ | | | | |
| Point 4: | ▽ | | | | |
| Point 5: | ▽ | | | | |
| Point 6: | ▽ | | | | |
| Point 7: | ▽ | | | | |
| Point 8: | ▽ | | | | |
| Point 9: | ▽ | | | | |
| Point 10: | ▽ | | | | |

Slope Check + ▽

Allowance Range Check

☐ Reagent Blank
☐ Calibration

Advanced Calibration Operation No ▽

Interval (RB/ACAL) ▽

<Point Cal. For Master Curve> No. of Correction Points ▽ Use Master Curve ▽ ☐ Lot Calibration

| | Calibrator | OD | Conc | OD Range Low | OD Range High |
|---|---|---|---|---|---|
| Point-1 | ▽ | | | | |
| Point-2 | ▽ | | | | |

Stability: Reagent Blank # Day # Hour; Calibration 30 Day 0 Hour

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

# User defined.
* Can also be run as RATE



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# DRI Ethyl Glucuronide Assay – Semiquantitative
# Beckman Coulter System Parameters, AU5800

Parameters | Specific Test Parameters

General | LIH | ISE | HbA1c | Calculated Test | Range

Test Name: ETGSQ ∇ | < | > | Type: Urine ∇ | Operation: Yes ∇

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Sample Volume | | 17.0 µL | Dilution | 0 µL | OD Limit | | | | |
| Pre-Dilution Rate | | 1 ∇ | Diluent Bottle | Outside ∇ | Min.OD | -2.00 | Max.OD | 3.00 | |
| Rgt. Volume | R1(R1-1) | 39 µL | Dilution | 0 µL | Reagent OD Limit | | | | |
| | R1-2 | µL | Dilution | µL | 1st. | Low -2.00 | High | 3.00 | |
| | | | | | Last | Low -2.00 | High | 3.00 | |
| | R2(R2-1) | 39 µL | Dilution | 0 µL | | | | | |
| | | | | | Dynamic Range | Low 0 | High | 2000 | |
| Common Rgt. Type | | None | Name | None | Correlation Factor | A 1 | B | 0 | |
| Wavelength | Pri | 340 ∇nm | Sec. | 410 ∇nm | Factor for Maker | A 1 | B | 0 | |
| Method | | FIXED1* ∇ | | | | | | | |
| Reaction Slope | | + ∇ | | | Onboard Stability Period | 30 Day | 0 Hour | | |
| Measuring Point1 1st | | 13 | Last | 17 | LIH Influence Check | No ∇ | | | |
| Measuring Point2 1st | | | Last | | Lipemia | ∇ | | | |
| Linearity Limit | | % | | | Icterus | ∇ | | | |
| Lag Time Check | | No ∇ | | | Hemolysis | ∇ | | | |

Parameters | Specific Test Parameters

General | LIH | ISE | HbA1c | Calculated Test | Range

Test Name: ETGSQ ∇ | < | > | Type: Urine ∇

Value/Flag: # ∇

Level: Low # High #

Specific Ranges:

| | Sex | From Year | From Month | To Year | To Month | Low | High |
|---|---|---|---|---|---|---|---|
| ☐ 1. | # ∇ | # | # | # | # | # | # |
| ☐ 2. | # ∇ | # | # | # | # | # | # |
| ☐ 3. | # ∇ | # | # | # | # | # | # |
| ☐ 4. | # ∇ | # | # | # | # | # | # |
| ☐ 5. | # ∇ | # | # | # | # | # | # |
| ☐ 6. | # ∇ | # | # | # | # | # | # |
| 7. Standard demographics | | | | | | # | # |
| 8. Not within expected values | | | | | | # | # |

Panic Value: Low # | High # | Unit ng/mL | Decimal Places #

Parameters | Calibration Parameters

Calibrators | Calibration Specific

General | ISE

Test Name: ETGSQ ∇ | < | > | Type: Urine ∇ | Cuvette . ∇

☐ Use Serum Cal.

Calibration Type: 5AB ∇ | Formula: Polygonal ∇ | Counts: 2 ∇

<Calibrator Parameters>

| | Calibrator | OD | Conc | Range Low | Range High |
|---|---|---|---|---|---|
| Point 1: | # ∇ | | 0.0 | -2.00 | 3.00 |
| Point 2: | # ∇ | | 100.0 | -2.00 | 3.00 |
| Point 3: | # ∇ | | 500.0 | -2.00 | 3.00 |
| Point 4: | # ∇ | | 1000.0 | -2.00 | 3.00 |
| Point 5: | # ∇ | | 2000.0 | -2.00 | 3.00 |
| Point 6: | ∇ | | | | |
| Point 7: | ∇ | | | | |
| Point 8: | ∇ | | | | |
| Point 9: | ∇ | | | | |
| Point 10: | ∇ | | | | |

Slope Check: + ∇

Allowance Range Check

☐ Reagent Blank

☐ Calibration

Advanced Calibration Operation: No ∇

Interval (RB/ACAL) ∇

<Point Cal. For Master Curve> | No. of Correction Points ∇ | Use Master Curve ∇ | ☐ Lot Calibration

| | Calibrator | OD | Conc | OD Range Low | OD Range High |
|---|---|---|---|---|---|
| Point-1 | ∇ | | | | |
| Point-2 | ∇ | | | | |

Stability: Reagent Blank # Day # Hour; Calibration 30 Day 0 Hour

MB Type Factor: | 1-Point Calibration Point: None ∇ | ☐ with Conc-0

# User defined.

* Can also be run as RATE1



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## Precision

Tests for within-run and total precision, evaluated with packaged reagents, controls and calibrators, yielded the following results:

**Qualitative Assay**
**500 ng/mL Cutoff**

| Controls | Low Control | Cutoff Cal | High Control |
|---|---|---|---|
| ***AU480*** (N=84) | | | |
| Mean Rate (mA/min) | 436.8 | 457.1 | 480.1 |
| Within-Run SD (mA/min) | 1.96 | 1.35 | 2.12 |
| Within-Run CV (%) | 0.5 | 0.3 | 0.4 |
| Total SD (mA/min) | 2.64 | 2.06 | 2.73 |
| Total CV (%) | 0.6 | 0.5 | 0.6 |
| ***AU640*** (N=60) | | | |
| Mean Rate (mA/min) | 382 | 401 | 423 |
| Within-Run SD (mA/min) | 2.6 | 1.6 | 3.3 |
| Within-Run CV (%) | 0.7 | 0.4 | 0.8 |
| Total SD (mA/min) | 4.1 | 5.5 | 6.0 |
| Total CV (%) | 1.1 | 1.4 | 1.4 |
| ***AU680*** (N=84) | | | |
| Mean Rate (mA/min) | 455.4 | 476.1 | 503.4 |
| Within-Run SD (mA/min) | 1.14 | 1.40 | 1.35 |
| Within-Run CV (%) | 0.3 | 0.3 | 0.3 |
| Total SD (mA/min) | 2.59 | 3.10 | 3.56 |
| Total CV (%) | 0.6 | 0.7 | 0.7 |
| ***AU5800*** (N=84) | | | |
| Mean Rate (mA/min) | 438.7 | 457.0 | 480.4 |
| Within-Run SD (mA/min) | 1.40 | 1.46 | 2.01 |
| Within-Run CV (%) | 0.3 | 0.3 | 0.4 |
| Total SD (mA/min) | 2.54 | 2.87 | 3.27 |
| Total CV (%) | 0.6 | 0.6 | 0.7 |


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## Precision, *continued*

**Qualitative Assay**
**1000 ng/mL Cutoff**

| Controls | Low Control | Cutoff Cal | High Control |
|---|---|---|---|
| ***AU480*** (N=80) | | | |
| Mean Rate (mA/min) | 530.0 | 561.2 | 590.8 |
| Within-Run SD (mA/min) | 2.64 | 2.58 | 2.53 |
| Within-Run CV (%) | 0.5 | 0.5 | 0.4 |
| Total SD (mA/min) | 2.85 | 2.78 | 2.83 |
| Total CV (%) | 0.5 | 0.5 | 0.5 |
| ***AU640*** (N=60) | | | |
| Mean Rate (mA/min) | 450 | 474 | 506 |
| Within-Run SD (mA/min) | 4.6 | 3.2 | 4.7 |
| Within-Run CV (%) | 1.0 | 2.2 | 0.9 |
| Total SD (mA/min) | 6.0 | 10.5 | 7.1 |
| Total CV (%) | 1.3 | 2.2 | 1.4 |
| ***AU680*** (N=80) | | | |
| Mean Rate (mA/min) | 557.6 | 589.3 | 620.4 |
| Within-Run SD (mA/min) | 1.90 | 3.00 | 2.93 |
| Within-Run CV (%) | 0.3 | 0.5 | 0.5 |
| Total SD (mA/min) | 2.96 | 4.52 | 4.07 |
| Total CV (%) | 0.5 | 0.8 | 0.7 |
| ***AU5800*** (N=84) | | | |
| Mean Rate (mA/min) | 524.4 | 554.2 | 584.2 |
| Within-Run SD (mA/min) | 4.95 | 5.05 | 4.91 |
| Within-Run CV (%) | 0.9 | 0.9 | 0.8 |
| Total SD (mA/min) | 7.26 | 7.30 | 7.59 |
| Total CV (%) | 1.4 | 1.3 | 1.3 |


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## Precision, *continued*

**Semiquantitative Assay**
**500 ng/mL Cutoff**

| Controls | Low Control | Cutoff Cal | High Control |
|---|---|---|---|
| ***AU480*** (N=84) | | | |
| Mean (ng/mL) | 407.6 | 507.1 | 646.4 |
| Within-Run SD (ng/mL) | 9.52 | 7.94 | 12.91 |
| Within-Run CV (%) | 2.3 | 1.6 | 2.0 |
| Total SD (ng/mL) | 11.99 | 8.76 | 13.31 |
| Total CV (%) | 2.9 | 1.7 | 2.1 |
| ***AU640*** (N=60) | | | |
| Mean (ng/mL) | 382 | 486 | 612 |
| Within-Run SD (ng/mL) | 17.0 | 9.7 | 21.6 |
| Within-Run CV (%) | 4.5 | 2.0 | 3.5 |
| Total SD (ng/mL) | 21.1 | 25.9 | 30.9 |
| Total CV (%) | 5.5 | 5.3 | 5.1 |
| ***AU680*** (N=84) | | | |
| Mean (ng/mL) | 400.8 | 489.6 | 647.1 |
| Within-Run SD (ng/mL) | 4.89 | 6.37 | 8.04 |
| Within-Run CV (%) | 1.2 | 1.3 | 1.2 |
| Total SD (ng/mL) | 9.47 | 10.89 | 12.08 |
| Total CV (%) | 2.4 | 2.2 | 1.9 |
| ***AU5800*** (N=84) | | | |
| Mean (ng/mL) | 412.3 | 499.7 | 639.5 |
| Within-Run SD (ng/mL) | 6.65 | 7.71 | 12.13 |
| Within-Run CV (%) | 1.6 | 1.5 | 1.9 |
| Total SD (ng/mL) | 7.88 | 11.20 | 14.58 |
| Total CV (%) | 1.9 | 2.2 | 2.3 |


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## Precision, *continued*

**Semiquantitative Assay**
**1000 ng/mL Cutoff**

| Controls | Low Control | Cutoff Cal | High Control |
|---|---|---|---|
| ***AU480*** (N=80) | | | |
| Mean (ng/mL) | 777.1 | 1007.8 | 1244.3 |
| Within-Run SD (ng/mL) | 19.40 | 19.96 | 20.17 |
| Within-Run CV (%) | 2.5 | 2.0 | 1.6 |
| Total SD (ng/mL) | 20.15 | 23.13 | 22.76 |
| Total CV (%) | 2.6 | 2.3 | 1.8 |
| ***AU640*** (N=60) | | | |
| Mean (ng/mL) | 810 | 996 | 1291 |
| Within-Run SD (ng/mL) | 26.8 | 25.8 | 39.5 |
| Within-Run CV (%) | 3.3 | 2.6 | 3.1 |
| Total SD (ng/mL) | 37.6 | 57.6 | 59.2 |
| Total CV (%) | 4.7 | 5.8 | 4.6 |
| ***AU680*** (N=80) | | | |
| Mean (ng/mL) | 781.3 | 1004.6 | 1241.7 |
| Within-Run SD (ng/mL) | 13.42 | 21.63 | 21.92 |
| Within-Run CV (%) | 1.7 | 2.2 | 1.8 |
| Total SD (ng/mL) | 21.15 | 33.19 | 31.78 |
| Total CV (%) | 2.7 | 3.3 | 2.6 |
| ***AU5800*** (N=84) | | | |
| Mean (ng/mL) | 771.3 | 990.4 | 1236.7 |
| Within-Run SD (ng/mL) | 28.99 | 21.56 | 31.23 |
| Within-Run CV (%) | 3.8 | 2.2 | 2.5 |
| Total SD (ng/mL) | 38.01 | 39.00 | 44.46 |
| Total CV (%) | 4.9 | 3.9 | 3.6 |

## Linearity

Nine levels of diluted calibrators were run against a single calibration curve and the linearity calculated.

The Ethyl Glucuronide assay recovered between 99.0% and 106.4% on the AU480.
The Ethyl Glucuronide assay recovered between 93.2% and 106.3% on the AU680.
The Ethyl Glucuronide assay recovered between 98.5% and 108.3% on the AU5800.

## Limit of Detection (LDD)

The negative calibrator was run against the same calibration curve for 21 replicates. The LDD is calculated as 2*SD.

The observed LDDs for DRI Ethyl Glucuronide on the AU480, AU680 and AU5800 were 13.5, 9.7, and 11.4 ng/mL, respectively.


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## Accuracy and Correlation

### Qualitative 500 ng/mL

Patient urine samples were assayed using the DRI Ethyl Glucuronide Assay on the Beckman Coulter AU480, AU640, AU680, and AU5800 and tested against the reference analyzer, the Hitachi 717.

| Qualitative (500 ng/mL Cutoff) Method Comparison | | | |
|---|---|---|---|
| | **Positive Agreement (%)** | **Negative Agreement (%)** | **Total Agreement (%)** |
| AU480 | 94.3% | 100.0% | 96.2% |
| AU640 | 97.9% | 100.0% | 99.0% |
| AU680 | 94.3% | 100.0% | 96.2% |
| AU5800 | 97.7% | 100.0% | 98.5% |

**DRI Ethyl Glucuronide Assay Qualitative (500 ng/mL) Method Comparison**

| AU480 | Hitachi 717 + | Hitachi 717 - |
|---|---|---|
| + | 83 | 0 |
| - | 5 | 42 |

| AU640 | Hitachi 717 + | Hitachi 717 - |
|---|---|---|
| + | 46 | 0 |
| - | 1 | 53 |

| AU680 | Hitachi 717 + | Hitachi 717 - |
|---|---|---|
| + | 83 | 0 |
| - | 5 | 42 |

| AU5800 | Hitachi 717 + | Hitachi 717 - |
|---|---|---|
| + | 86 | 0 |
| - | 2 | 42 |



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## Accuracy and Correlation

### Qualitative 1000 ng/mL

Patient urine samples were assayed using the DRI Ethyl Glucuronide Assay on the Beckman Coulter AU480, AU640, AU680, and AU5800 and tested against the reference analyzer, the Hitachi 717.

| Qualitative (1000 ng/mL Cutoff) Method Comparison | | | |
|---|---|---|---|
| | **Positive Agreement (%)** | **Negative Agreement (%)** | **Total Agreement (%)** |
| AU480 | 98.5% | 100.0% | 99.2% |
| AU640 | 93.8% | 100.0% | 98.0% |
| AU680 | 95.4% | 100.0% | 97.7% |
| AU5800 | 98.5% | 96.9% | 97.7% |

**DRI Ethyl Glucuronide Assay Qualitative (1000 ng/mL) Method Comparison**

| AU480 | Hitachi 717 + | Hitachi 717 - |
|---|---|---|
| + | 64 | 0 |
| - | 1 | 65 |

| AU640 | Hitachi 717 + | Hitachi 717 - |
|---|---|---|
| + | 30 | 0 |
| - | 2 | 68 |

| AU680 | Hitachi 717 + | Hitachi 717 - |
|---|---|---|
| + | 62 | 0 |
| - | 3 | 65 |

| AU5800 | Hitachi 717 + | Hitachi 717 - |
|---|---|---|
| + | 64 | 2 |
| - | 1 | 63 |



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## Accuracy and Correlation

### Semiquantitative 500 ng/mL

Patient urine samples were assayed using the DRI Ethyl Glucuronide Assay on the Beckman Coulter AU480, AU640, AU680, and AU5800 and tested against the reference analyzer, the Hitachi 717.

| Semiquantitative (500 ng/mL Cutoff) Method Comparison | | | |
|---|---|---|---|
| | **Positive Agreement (%)** | **Negative Agreement (%)** | **Total Agreement (%)** |
| AU480 | 98.8% | 100.0% | 99.2% |
| AU640 | 100.0% | 100.0% | 100.0% |
| AU680 | 100.0% | 97.9% | 99.2% |
| AU5800 | 100.0% | 100.0% | 100.0% |

**DRI Ethyl Glucuronide Assay**
**Semiquantitative (500 ng/mL) Method Comparison**

**AU480**

| | | Hitachi 717 + | Hitachi 717 - |
|---|---|---|---|
| | + | 83 | 0 |
| | - | 1 | 46 |

**AU640**

| | | Hitachi 717 + | Hitachi 717 - |
|---|---|---|---|
| | + | 46 | 0 |
| | - | 0 | 54 |

**AU680**

| | | Hitachi 717 + | Hitachi 717 - |
|---|---|---|---|
| | + | 83 | 1 |
| | - | 0 | 46 |

**AU5800**

| | | Hitachi 717 + | Hitachi 717 - |
|---|---|---|---|
| | + | 84 | 0 |
| | - | 0 | 46 |



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## Accuracy and Correlation

### Semiquantitative 1000 ng/mL

Patient urine samples were assayed using the DRI Ethyl Glucuronide Assay on the Beckman Coulter AU480, AU640, AU680, and AU5800 and tested against the reference analyzer, the Hitachi 717.

| Semiquantitative (1000 ng/mL Cutoff) Method Comparison | | | |
|---|---|---|---|
| | **Positive Agreement (%)** | **Negative Agreement (%)** | **Total Agreement (%)** |
| AU480 | 98.4% | 98.5% | 98.5% |
| AU680 | 100.0% | 98.5% | 99.2% |
| AU5800 | 98.4% | 100.0% | 99.2% |

**DRI Ethyl Glucuronide Assay**
**Semiquantitative (1000 ng/mL) Method Comparison**

**AU480**

| | | Hitachi 717 + | Hitachi 717 - |
|---|---|---|---|
| | + | 63 | 1 |
| | - | 1 | 65 |

**AU680**

| | | Hitachi 717 + | Hitachi 717 - |
|---|---|---|---|
| | + | 63 | 1 |
| | - | 0 | 66 |

**AU5800**

| | | Hitachi 717 + | Hitachi 717 - |
|---|---|---|---|
| | + | 63 | 0 |
| | - | 1 | 66 |



*End*



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