

DRI™ ETHYL GLUCURONIDE APPLICATION

QuidelOrtho Vitros® XT 7600 INTEGRATED SYSTEM, Vitros® 5600 INTEGRATED SYSTEM, AND Vitros® 4600 CHEMISTRY SYSTEM

Reference No. 10015894

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 Criminal Justice and Forensic Use 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. For package inserts, visit www.quidelortho.com > Resources > MicroTip Partnership Assays (MPA).

Ordering Information

Please place your order with QuidelOrtho. Ordering information available on www.quidelortho.com.

Technical Support Information

Contact QuidelOrtho for technical support. Contact information available on www.quidelortho.com.



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

Reagent Pack Storage

Unopened reagents are stable until the expiration date when stored at 2 to 8°C.

Reagents stored in UDxx reagent packs onboard the analyzer are stable for 30 days.

Reagents are supplied liquid ready-to-use.

The UDxx reagent pack may be filled up to 15 mL of Reagent A in UDxx/A bottle and 15 mL of Reagent B in UDxx/B bottle and provides 144 tests.

| R1 (mL) in UDxx/A | R2 (mL) in UDxx/B | Tests/pack |
|-------------------|-------------------|------------|
| 15 | 15 | 144 |

NOTE: Once the individual UDxx pack number is selected for use during the protocol programming, it is the only UDxx pack number to use for this protocol.

Special Reagent Packs for User Defined Assays

(Please order from QuidelOrtho; not available from Microgenics)

| Part Number | Description | Quantity |
|-------------|---------------------|------------|
| 680 2246 | UD01 Packs (Empty) | 1 BOX/6PKS |
| 680 2247 | UD02 Packs (Empty) | 1 BOX/6PKS |
| 680 2248 | UD03 Packs (Empty) | 1 BOX/6PKS |
| 680 2249 | UD04 Packs (Empty) | 1 BOX/6PKS |
| 680 2250 | UD05 Packs (Empty) | 1 BOX/6PKS |
| 680 2251 | UD06 Packs (Empty) | 1 BOX/6PKS |
| 680 2252 | UD07 Packs (Empty) | 1 BOX/6PKS |
| 680 2253 | UD08 Packs (Empty) | 1 BOX/6PKS |
| 680 2254 | UD09 Packs (Empty) | 1 BOX/6PKS |
| 680 2255 | UD10 Packs (Empty) | 1 BOX/6PKS |
| 684 4449 | UD11 Packs (Empty) | 1 BOX/6PKS |
| 684 4448 | UD12 Packs (Empty) | 1 BOX/6PKS |
| 684 4445 | UD13 Packs (Empty) | 1 BOX/6PKS |
| 684 4442 | UD14 Packs (Empty) | 1 BOX/6PKS |
| 684 4447 | UD15 Packs (Empty) | 1 BOX/6PKS |
| 684 4444 | UD16 Packs (Empty) | 1 BOX/6PKS |
| 684 4441 | UD17 Packs (Empty) | 1 BOX/6PKS |
| 684 4446 | UD18 Packs (Empty) | 1 BOX/6PKS |
| 684 4443 | UD19 Packs (Empty) | 1 BOX/6PKS |
| 684 4440 | UD20 Packs (Empty) | 1 BOX/6PKS |
| 680 2256 | UDDL1 Packs (Empty) | 1 BOX/6PKS |
| 680 2257 | UDDL2 Packs (Empty) | 1 BOX/6PKS |

Results and Data Interpretation

For the Qualitative assay, the Vitros® XT 7600 System, Vitros® 5600 System, and Vitros® 4600 System can report both a unit-less Index number and a NEG / POS classification. The assay is calibrated at the cutoff concentration so that the Index number less than the cutoff value are negative and those greater than the cutoff value are positive.

NOTE: *Qualitative results must only be reported as Negative or Positive. Unit-less Index numbers cannot be used in reportable results.*

For the Semiquantitative assay, the Vitros® XT 7600 System, Vitros® 5600 System, and Vitros® 4600 System can report both Semiquantitative numbers in ng/mL and a NEG/POS classification. The POS classification will also be given on samples above the Semiquantitative reporting range. Sample results above the high calibrator should be diluted with negative urine and retested.

Out of Range Error Codes

A very high analyte sample can produce an absorbance outside the Vitros® System photometer range and will result in a CB error code. Sample results above the high calibrator should be diluted with negative urine and retested.

With the Semiquantitative assay, a sample above the logit-log4 spline prediction range, but within the System photometer range, will produce an ER error. Sample results above the high calibrator should be diluted with negative urine and retested.

Calibration Frequency

It is recommended that recalibration occur after a reagent pack change, after a calibrator lot change, after performance of monthly instrument maintenance and as required following the laboratory's quality control procedure.

DRI Ethyl Glucuronide Assay – Qualitative QuidelOrtho Vitros® XT 7600 System, Vitros® 5600 System, and Vitros® 4600 System Parameters

Full Assay Name: Ethyl Glu Qual Version Date: 09/13/2017
Short Assay Name: EG500 or EG1K Fluid Type: Urine
Assay Model Type: 2 Point Rate Template: *2Pt R1-S-R2
Cal Model Type: Linear Calibrator Bottles: 2 Reagent Reps per Cal: 2

Reagent Lot Information

On-Board Stability: 30 Days
Reagent Lot Num: Kit Lot
Shelf Exp. Date: Kit Exp Date

Edit Dilution Parameters

Diluent: DATDIL Standard Dilution Factor: 1.0
Reflex Dilution: OFF Dilution Factor: 1.0
Reduction Factor: 1.0

Edit Result Parameters

NOTE: For XT 7600 / 5600 / 4600 only enter qualitative ranges and the Measuring (Reportable) range

Units: _____ Number of Qualitative Ranges: 2

Significant Digits: 5 Precision Digits: 1 1. NEGATIVE

User Adjusted Parameters 2. POSITIVE 500 or greater (**or enter 1000**)

Slope: 1.0 Intercept: 0.0 Report Qualitative Result Outside of Range: Yes

CuveTip Exp Time: 35 Temp Sens : No Measuring (Reportable) 0 to 10000

(More Assay Parm) – Edit 2 Pt Rate Additional Parameters

Initial Abs. Limits: -0.20 to 3.50

Second Abs. Limits: -0.20 to 3.50

Antigen Excess Factor: 9.0

DRI Ethyl Glucuronide Assay – Qualitative
QuidelOrtho Vitros® XT 7600 System, Vitros® 5600 System, and Vitros® 4600 System
Parameters, *continued*

Edit Protocol Parameters

| Step | Volume | Pack ID | Seconds | Wavelength |
|---------------|---------|---------|---------|------------|
| 1. Reagent | 80 µL | UDxx /A | | |
| 2. Incubation | | | 0.0 | |
| 3. Sample | 35.0 µL | | | |
| 4. Incubation | | | 304.0 | |
| 5. Reagent | 80 µL | UDxx /B | | |
| 6. Incubation | | | 38.0 | |
| 7. Read | | | | 340 nm |
| 8. Incubation | | | 76.0 | |
| 9. Read | | | | 340 nm |

Edit Calibration Parameters

| Bottle # | Dil Factor | Cal Rep Resp Range | Calibrator Lot: <u>Cal Kit lot</u> |
|----------|------------|--------------------|---------------------------------------|
| 1 | <u>1.0</u> | <u>0.20</u> | Cal value: <u>0</u> |
| 2 | <u>1.0</u> | <u>0.20</u> | Cal Value: <u>500</u> (or enter 1000) |

(More Cal Parms) – Edit Linear or Logit/Log Additional Parameters

Monotonicity: Increase

Max Resp High: 3.00 Min. Resp. High: 3.00 Cal Fit Goodness Limit: 0.990

Max Resp. Low: -3.00 Min Resp. Low: -3.00

Edit Triple Read Parameters

| | Reportable Conc. | Triple Read Limit |
|------------------|-------------------|---|
| Reportable Min.: | <u>0</u> | <u>40 for 500 cutoff (80 for 1000 cutoff)</u> |
| Critical Conc.: | <u>500 (1000)</u> | <u>8.0</u> % |
| Reportable Max.: | <u>10000</u> | <u>8.0</u> % |

Comments: N/A

DRI Ethyl Glucuronide Assay – Semiquantitative QuidelOrtho Vitros® XT 7600 System, Vitros® 5600 System, and Vitros® 4600 System Parameters

Full Assay Name: Ethyl Glu SemiQuant Version Date: 09/13/2017
Short Assay Name: EGLU Fluid Type: Urine
Assay Model Type: 2 Point Rate Template: *2Pt R1-S-R2
Cal Model Type: Logit/Log4 Calibrator Bottles: 5 Reagent Reps per Cal: 2

Reagent Lot Information

On-Board Stability: 30 Days

Reagent Lot Num: Kit Lot

Shelf Exp. Date: Kit Exp Date

Edit Dilution Parameters

Diluent: DATDIL Standard Dilution Factor: 1.0

Reflex Dilution: OFF Dilution Factor: 1.0

Reduction Factor: 1.0

Edit Result Parameters

NOTE: For XT 7600 / 5600 / 4600 only enter qualitative ranges and the Measuring (Reportable) range

Units: ng/mL

Number of Qualitative Ranges: 2

Significant Digits: 5 Precision Digits: 1

1. NEGATIVE

User Adjusted Parameters

2. POSITIVE 500 or greater (**or enter 1000**)

Slope: 1.0 Intercept: 0.0

Report Qualitative Result Outside of Range: Yes

CuveTip Exp Time: 35 Temp Sens : No

Measuring (Reportable) 0 to 2000

(More Assay Parm) – Edit 2 Pt Rate Additional Parameters

Initial Abs. Limits: -0.20 to 3.50

Second Abs. Limits: -0.20 to 3.50

Antigen Excess Factor: 9.0

DRI Ethyl Glucuronide Assay – Semiquantitative
QuidelOrtho Vitros® XT 7600 System, Vitros® 5600 System, and Vitros® 4600 System
Parameters, *continued*

Edit Protocol Parameters

| Step | Volume | Pack ID | Seconds | Wavelength |
|---------------|---------|---------|---------|------------|
| 1. Reagent | 80 µL | UDxx /A | | |
| 2. Incubation | | | 0.0 | |
| 3. Sample | 35.0 µL | | | |
| 4. Incubation | | | 304.0 | |
| 5. Reagent | 80 µL | UDxx /B | | |
| 6. Incubation | | | 38.0 | |
| 7. Read | | | | 340 nm |
| 8. Incubation | | | 76.0 | |
| 9. Read | | | | 340 nm |

Edit Calibration Parameters

| Bottle # | Dil Factor | Cal Rep Resp Range | Calibrator Lot: <u>Cal Kit lot</u> |
|----------|------------|--------------------|------------------------------------|
| 1 | <u>1.0</u> | <u>0.20</u> | Cal value: <u>0</u> |
| 2 | <u>1.0</u> | <u>0.20</u> | Cal Value: <u>100</u> |
| 3 | <u>1.0</u> | <u>0.20</u> | Cal Value: <u>500</u> |
| 4 | <u>1.0</u> | <u>0.20</u> | Cal Value: <u>1000</u> |
| 5 | <u>1.0</u> | <u>0.20</u> | Cal Value: <u>2000</u> |

(More Cal Parms) – Edit Linear or Logit/Log Additional Parameters

Monotonicity: Increase

Max Resp High: 3.00

Min. Resp. High: 3.00

Cal Fit Goodness Limit: 0.990

Max Resp. Low: -3.00

Min Resp. Low: -3.00

**DRI Ethyl Glucuronide Assay – Semiquantitative
QuidelOrtho Vitros® XT 7600 System, Vitros® 5600 System, and Vitros® 4600 System
Parameters, *continued***

Edit Triple Read Parameters

| | Reportable Conc. | Triple Read Limit |
|------------------|-------------------|---|
| Reportable Min.: | <u>0</u> | <u>40 for 500 cutoff (80 for 1000 cutoff)</u> |
| Critical Conc.: | <u>500 (1000)</u> | <u>8.0</u> % |
| Reportable Max.: | <u>2000</u> | <u>8.0</u> % |

Comments: N/A

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