Microgenics Corporation
*Part of Thermo Fisher Scientific*

# DRI™ ECSTASY APPLICATION
# ORTHO CLINICAL DIAGNOSTICS VITROS® XT 7600 INTEGRATED SYSTEM, VITROS® 5600 INTEGRATED SYSTEM, VITROS® 4600 CHEMISTRY SYSTEM, AND VITROS® 5,1 FS CHEMISTRY SYSTEM

Reference No. 100075 and 100076

**This Application is Intended for the Qualitative and Semiquantitative Determination of Ecstasy Drugs in Human Urine**

IVD 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. For package inserts, visit www.orthoclinicaldiagnostics.com > Ortho Care > Technical Documents > MicroTip Partnership Assays (MPA).

## Ordering Information

Please place your order with Ortho Clinical Diagnostics. Ordering information available on www.orthoclinicaldiagnostics.com.

## Technical Support Information

Contact Ortho Clinical Diagnostics for technical support. Contact information available on www.orthoclinicaldiagnostics.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**

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

## 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 28 days.

Reagents are supplied liquid ready-to-use. As supplied, the Antibody/Substrate Reagent A (100 mL) and the Enzyme Conjugate Reagent E (100mL) can fill multiple VITROS reagent packs. 13 mL of Reagent A in a UDxx/A bottle and 13 mL of Reagent E in a UDxx/B bottles provides 100 tests. Filling 17 mL of each reagent (maximum fill for R2 bottle) provides 135 tests.

***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 Ortho Clinical Diagnostics; 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 |

## Calibration Frequency

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



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

## 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 VITROS® 5,1 FS System will only provide a unit-less Index number. The assay is calibrated at the cutoff concentration so Index numbers 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. The VITROS® 5,1 FS System will only provide semiquantitative ng/mL results. 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 on the VITROS® XT 7600 System, VITROS® 5600 System, VITROS® 4600 System or VITROS® 5,1 FS System a sample above the logit/log4 spline prediction range, but within the analyzer photometer range, will produce an ER error. Sample results above the high calibrator should be diluted with negative urine and retested.



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

## DRI Ecstasy Assay-Qualitative 500 ng/mL Cutoff
## Ortho Clinical Diagnostics VITROS® XT 7600 System, VITROS® 5600 System, VITROS® 4600 System, and VITROS® 5,1 FS System Parameters

Full Assay Name: Ecstasy Qual at 500 Version Date: 4/29/2011

Short Assay Name: XT500 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: 28 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**

**For 5,1 FS, just enter Measuring (Reportable) range**

Units:

Significant Digits: 4 Precision Digits: 0

User Adjusted Parameters

Slope: 1.0 Intercept: 0.0

CuveTip Exp Time: 35 Temp Sens : No

Number of Qualitative Ranges: 2

1. NEGATIVE

2. POSITIVE 500 or greater

Report Qualitative Result Outside of Range: Yes

Measuring (Reportable) 0 to 9999

**(More Assay Parms) – Edit 2 Pt Rate Additional Parameters**

Initial Abs. Limits: -0.20 to 2.70

Second Abs. Limits: -0.20 to 2.70

Antigen Excess Factor: 9.0

---



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

## DRI Ecstasy Assay-Qualitative 500 ng/mL Cutoff
## Ortho Clinical Diagnostics VITROS® XT 7600 System, VITROS® 5600 System, VITROS® 4600 System, and VITROS® 5,1 FS System Parameters, *continued*

### Edit Protocol Parameters

| | Step | Volume | Pack ID | Seconds | Wavelength |
|---|---|---|---|---|---|
| 1. | Reagent | 100 µL | UDxx /A | | |
| 2. | Incubation | | | 0.0 | |
| 3. | Sample | 8.0 | | | |
| 4. | Incubation | | | 304.0 | |
| 5. | Reagent | 100 µL | UDxx /B | | |
| 6. | Incubation | | | 114 | |
| 7. | Read | | | | 340 nm |
| 8. | Incubation | | | 114 | |
| 9. | Read | | | | 340 nm |

### Edit Calibration Parameters

| Bottle # | Dil Factor | Cal Rep Resp Range | Calibrator Lot: *Cal Kit lot* |
|---|---|---|---|
| 1 | 1.0 | 0.20 | Cal value: *0* |
| 2 | 1.0 | 0.20 | Cal Value: 500 |

---

### (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.: | 0 | 200 |
| Critical Conc.: | 500 | 8.0 % |
| Reportable Max.: | 9999 | 8.0 % |

---



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

## DRI Ecstasy Assay-Semiquantitative 500 ng/mL Cutoff
## Ortho Clinical Diagnostics VITROS® XT 7600 System, VITROS® 5600 System, VITROS® 4600 System, and VITROS® 5,1 FS System Parameters

Full Assay Name: Ecstasy Semi-Quant  Version Date: 4/29/2011

Short Assay Name: XTC  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: 28 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: 20.0

Reduction Factor: 1.0

---

**Edit Result Parameters**

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

**For 5,1 FS, just enter Measuring (Reportable) range**

Units: ng/mL

Significant Digits: 5  Precision Digits: 1

User Adjusted Parameters

Slope: 1.0  Intercept: 0.0

CuveTip Exp Time: 35  Temp Sens : No

Number of Qualitative Ranges: 2

1. NEGATIVE

2. POSITIVE  500 or greater

Report Qualitative Result Outside of Range: Yes

Measuring (Reportable) 100 to 1000

**(More Assay Parms) – Edit 2 Pt Rate Additional Parameters**

Initial Abs. Limits: -0.20 to 2.70

Second Abs. Limits: -0.20 to 2.70

Antigen Excess Factor: 9.0

---



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

## DRI Ecstasy Assay-Semiquantitative 500 ng/mL Cutoff
## Ortho Clinical Diagnostics VITROS® XT 7600 System, VITROS® 5600 System, VITROS® 4600 System, and VITROS® 5,1 FS System Parameters, *continued*

### Edit Protocol Parameters

| | Step | Volume | Pack ID | Seconds | Wavelength |
|---|---|---|---|---|---|
| 1. | Reagent | 100 µL | UDxx /A | | |
| 2. | Incubation | | | 0.0 | |
| 3. | Sample | 8 | | | |
| 4. | Incubation | | | 304.0 | |
| 5. | Reagent | 100 µL | UDxx /B | | |
| 6. | Incubation | | | 114 | |
| 7. | Read | | | | 340 nm |
| 8. | Incubation | | | 114 | |
| 9. | Read | | | | 340 nm |

### Edit Calibration Parameters

| Bottle # | Dil Factor | Cal Rep Resp Range | Calibrator Lot: *Cal Kit lot* |
|---|---|---|---|
| 1 | 1.0 | 0.20 | Cal value: *0* |
| 2 | 1.0 | 0.20 | Cal Value: 250 |
| 3 | 1.0 | 0.20 | Cal Value: 500 |
| 4 | 1.0 | 0.20 | Cal Value: 750 |
| 5 | 1.0 | 0.20 | Cal Value: 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.: | 100 | 200 |
| Critical Conc.: | 500 | 8.0 % |
| Reportable Max.: | 1000 | 8.0 % |



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

*End*



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