# DRI® Ecstasy Assay Application – BECKMAN COULTER® UniCel® DxC and Synchron® System(s)

Beckman Coulter Reorder Number A39935

**Homogeneous enzyme immunoassay for the qualitative or semi-quantitative determination of ecstasy drugs in human urine.**

For In Vitro Diagnostic 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 storage, quality control, and additional performance data.**

**Ordering Information**

Materials available from your local Beckman Coulter Representative:

| Item | Beckman Coulter Reorder Number |
|---|---|
| DRI® Ecstasy Assay Kit (100 mL) | A39935 |
| DRI® Negative Calibrator | A44121 |
| DRI® Ecstasy 250 ng/mL Calibrator | A39936 |
| DRI® Ecstasy 500 ng/mL Calibrator | A39937 |
| DRI® Ecstasy 750 ng/mL Calibrator | A39938 |
| DRI® Ecstasy 1000 ng/mL Calibrator | A40566 |
| MGC Select DAU Control Set | A40567 |
| User-Defined Reagent Cartridge (pkg. of 12) | 442835 |

For Technical Support please contact your local Beckman Coulter Representative.

**Reagent Storage**

Refer to the package insert for information on reagent storage.

NOTE:
It is not recommended to leave the reagent on-board for more than 60 days.

**Procedure for Analyzer**

Refer to the operator's manuals for information on analyzer operation.
Dispense adequate amounts of Antibody/Substrate Reagent A and Enzyme Conjugate Reagent E into appropriate compartments of a User Defined Cartridge (PN 442835) as shown in the table below:

| | **User Defined Cartridge** | |
|---|---|---|
| **DRI® Ecstasy Assay Kit** | Compartment A | Compartment B |
| Antibody/Substrate Reagent A | 48 mL | |
| Enzyme Conjugate Reagent E | | 18 mL |

**Calibrator Information**

Refer to the package insert for information on calibration.
To use qualitative mode monitoring, calibration shall be carried out every 14 days or as indicated by control recovery.
To use semi-quantitative mode monitoring, calibration shall be carried out every 14 days or as indicated by control recovery.

# Application Parameter

**Parameters** DRI Ecstasy Assay chemistry parameter for **qualitative** mode on Synchron System(s).

| **INSTRUMENT PARAMETERS:** | **SYNCHRON CX** | **UniCel DxC Synchron LX** |
|---|---|---|
| Chemistry Name | Ecstasy | NA[a] |
| Test Name | XTCX | XTCX |
| Reaction Type: | Rate 1 | Rate 1 |
| Units | ng/mL | mA/min |
| Decimal Precision/Precision: | X.X | X.X |
| Reaction Direction: | Positive | Positive |
| Calculation Factor: | 0 | 1000 |
| Math Model: | Linear | DAT |
| Cal. Time Limit: | 336 | 336 |
| Number of Calibrators: | 2 | 3 |
| #1 | 0.0 | 0.0 |
| #2 | 500.0 | 500.0 |
| #3 | | 1000.0 |
| #4 | | |
| #5 | | |
| #6 | | |
| Primary Wavelength: | 340 nm | 340 nm |
| Secondary Wavelength: | 650 nm | 650 nm |
| Sample Volume: | 15 µL | 10 µL |
| **REAGENTS:** | | |
| Primary Inject (first)/First Inject | | |
| Compartment/Component: | A | A |
| Volume/Dispense Volume: | 200 µL | 125 µL |
| Add Time/Inject Time: | NA[a] | NA[a] |
| Primary Inject (first)/Second Inject | | |
| Compartment/Component: | None | None |
| Volume/Dispense Volume: | 0 µL | NA[a] |
| Add Time/Inject Time: | NA[a] | -180[a&b] |
| Second Inject/Third Inject | | |
| Compartment/Component: | B | B |
| Volume/Dispense Volume: | 75 µL | 75 µL |
| Add Time/Inject Time: | 368 sec | 276 sec |
| **REAGENTS:** | | |
| Blank | | |
| Start Read: | 237 sec | 292 sec |

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| INSTRUMENT PARAMETERS: | SYNCHRON CX | UniCel DxC Synchron LX |
|---|---|---|
| End Read: | 300 sec | 308 sec |
| Reaction 1 | | |
| Start Read: | 96 sec | 336 sec |
| End Read: | 144 sec | 396 sec |
| Reaction 2 | | |
| Start Read: | NA[a] | NA[a] |
| End Read: | NA[a] | NA[a] |
| USABLE RESULT RANGE: | | |
| Lower Limit: | 0.000 [b] | 0.000 [b] |
| Upper Limit: | 99999.999 [b] | 99999.999 [b] |
| ERROR DETECTION LIMITS: | | |
| **Reagent Blank/Blank** | | |
| ABS Low Limit: | -1.5[b] | -1.5 [b] |
| ABS High Limit: | 1.5 [b] | 2.2 [b] |
| Rate Low Limit: | NA[a] | -1.5 [b] |
| Rate High Limit: | NA[a] | 2.200 [b] |
| Mean Deviation: | NA[a] | 2.200 [b] |
| **Reaction/Reaction 1** | | |
| ABS Low Limit: | -1.5 [b] | -1.5 [b] |
| ABS High Limit: | 1.5 [b] | 2.2 [b] |
| Rate Low Limit: | NA[a] | -1.5 [b] |
| Rate High Limit: | NA[a] | 2.200 [b] |
| Mean Deviation: | NA[a] | 2.200 [b] |
| Reaction 2 | | |
| ABS Low Limit: | NA[a] | -1.5 [b] |
| ABS High Limit: | NA[a] | 2.2 [b] |
| Rate Low Limit: | NA[a] | -1.5 [b] |
| Rate High Limit: | NA[a] | 2.200 [b] |
| Mean Deviation: | NA[a] | 2.200 [b] |
| SUBSTRATE DEPLETION | | |
| Initial Rate: | 99.999 | 99.999 |
| Delta ABS: | 1.5 [b] | 2.2 [b] |
| MULTI POINT SPAN: | 0.000 [b] | 0.000 [b] |

[a] NA=Not applicable
[b] Denotes default value

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**Parameters** DRI Ecstasy Assay chemistry parameter for **semi-quantitative** mode on the Synchron System(s).

| **INSTRUMENT PARAMETERS:** | **SYNCHRON CX** | **UniCel DxC Synchron LX** |
|---|---|---|
| Chemistry Name | Ecstasy | NA[a] |
| Test Name | XTCX | XTCX |
| Reaction Type: | Rate 1 | Rate 1 |
| Units | ng/mL | ng/mL |
| Decimal Precision/Precision: | X.X | X.X |
| Reaction Direction: | Positive | Positive |
| Calculation Factor: | 0 | 1 |
| Math Model: | 1 | 1 |
| Cal. Time Limit: | 336 | 336 |
| Number of Calibrators: | 5 | 5 |
| #1 | 0.0 | 0.0 |
| #2 | 250.0 | 250.0 |
| #3 | 500.0 | 500.0 |
| #4 | 750.0 | 750.0 |
| #5 | 1000.0 | 1000.0 |
| #6 | | |
| Primary Wavelength: | 340 nm | 340 nm |
| Secondary Wavelength: | 650 nm | 650 nm |
| Sample Volume: | 15 µL | 10 µL |
| **REAGENTS:** | | |
| Primary Inject (first)/First Inject | | |
| Compartment/Component: | A | A |
| Volume/Dispense Volume: | 200 µL | 125 µL |
| Add Time/Inject Time: | NA[a] | NA[a] |
| Primary Inject (first)/Second Inject | | |
| Compartment/Component: | None | None |
| Volume/Dispense Volume: | | NA[a] |
| Add Time/Inject Time: | NA[a] | -180[a&b] |
| Second Inject/Third Inject | | |
| Compartment/Component: | B | B |
| Volume/Dispense Volume: | 75 µL | 75 µL |
| Add Time/Inject Time: | 368 sec | 276 sec |
| **REAGENTS:** | | |
| Blank | | |
| Start Read: | 237 sec | 292 sec |

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| INSTRUMENT PARAMETERS: | SYNCHRON CX | UniCel DxC Synchron LX |
|---|---|---|
| End Read: | 300 sec | 308 sec |
| Reaction 1 | | |
| Start Read: | 96 sec | 336 sec |
| End Read: | 144 sec | 396 sec |
| Reaction 2 | | |
| Start Read: | NA[a] | NA[a] |
| End Read: | NA[a] | NA[a] |
| USABLE RESULT RANGE: | | |
| Lower Limit: | 0.00 | 0.00 |
| Upper Limit: | 1000.0 | 1000.0 |
| ERROR DETECTION LIMITS: | | |
| **Reagent Blank/Blank** | | |
| ABS Low Limit: | -1.5[b] | -1.5[b] |
| ABS High Limit: | 1.5[b] | 2.2[b] |
| Rate Low Limit: | NA[a] | -1.5[b] |
| Rate High Limit: | NA[a] | 2.200[b] |
| Mean Deviation: | NA[a] | 2.200[b] |
| **Reaction/Reaction 1** | | |
| ABS Low Limit: | -1.5[b] | -1.5[b] |
| ABS High Limit: | 1.5[b] | 2.2[b] |
| Rate Low Limit: | NA[a] | -1.5[b] |
| Rate High Limit: | NA[a] | 2.200[b] |
| Mean Deviation: | NA[a] | 2.200[b] |
| Reaction 2 | | |
| ABS Low Limit: | NA[a] | -1.5[b] |
| ABS High Limit: | NA[a] | 2.2[b] |
| Rate Low Limit: | NA[a] | -1.5[b] |
| Rate High Limit: | NA[a] | 2.200[b] |
| Mean Deviation: | NA[a] | 2.200[b] |
| SUBSTRATE DEPLETION | | |
| Initial Rate: | 99.999[b] | 99.999[b] |
| Delta ABS: | 1.5[b] | 2.2[b] |
| MULTI POINT SPAN: | | |
| (1-2) | 0.004 | 0.009 |
| (2-3) | 0.024 | 0.046 |
| (3-4) | 0.031 | 0.037 |
| (4-5) | 0.016 | 0.013 |
| (5-1) | 0.082 | 0.106 |

[a] NA=Not applicable
[b] Denotes default value

## Results and Data Interpretation

Refer to the package insert for information on data interpretation.

**Typical Precision**

A properly operating Synchron system should exhibit precision values less than or comparable to the following:

**Within-run Precision (Qualitative)**

| | CX4 | | | DxC600 | | | LX20 | | |
|---|---|---|---|---|---|---|---|---|---|
| Rate mA/min | Mean | SD | **%CV** | Mean | SD | **%CV** | Mean | SD | **%CV** |
| Negative Control (375 ng/mL) | 83 | 0.76 | **0.91** | 115.6 | 1.50 | **1.29** | 118.3 | 1.77 | **1.49** |
| Cutoff Calibrator (500 ng/mL) | 102 | 0.83 | **0.81** | 146.2 | 1.95 | **1.33** | 149.6 | 1.91 | **1.28** |
| Positive Control (625 ng/mL) | 123 | 0.73 | **0.60** | 172.9 | 1.42 | **0.82** | 176.9 | 2.16 | **1.22** |

**Total Run Precision (Qualitative)**

| | CX4 | | | DxC600 | | | LX20 | | |
|---|---|---|---|---|---|---|---|---|---|
| Rate mA/min | Mean | SD | **%CV** | Mean | SD | **%CV** | Mean | SD | **%CV** |
| Negative Control (375 ng/mL) | 83 | 1.00 | **1.20** | 116 | 2.45 | **2.12** | 118 | 3.96 | **3.34** |
| Cutoff Calibrator (500 ng/mL) | 102 | 1.19 | **1.16** | 146 | 3.36 | **2.20** | 150 | 3.92 | **2.62** |
| Positive Control (625 ng/mL) | 123 | 1.08 | **0.89** | 173 | 3.08 | **1.78** | 177 | 4.25 | **2.40** |

**Within-run Precision (Semi-quantitative)**

| | CX4 | | | DxC600 | | | LX20 | | |
|---|---|---|---|---|---|---|---|---|---|
| Conc. ng/mL | Mean | SD | **%CV** | Mean | SD | **%CV** | Mean | SD | **%CV** |
| Negative Control (375 ng/mL) | 342.4 | 4.83 | **1.33** | 361.7 | 7.64 | **2.11** | 368.6 | 6.68 | **1.81** |
| Cutoff Calibrator (500 ng/mL) | 498.2 | 5.04 | **1.01** | 502.6 | 8.01 | **1.59** | 502.3 | 10.17 | **2.03** |
| Positive Control (625 ng/mL) | 633.5 | 6.67 | **1.05** | 634.8 | 13.07 | **2.06** | 629.7 | 11.49 | **1.82** |

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**Total Precision (Semi-quantitative)**

| | CX4 | | | DxC600 | | | LX20 | | |
|---|---|---|---|---|---|---|---|---|---|
| Conc. ng/mL | Mean | SD | **%CV** | Mean | SD | **%CV** | Mean | SD | **%CV** |
| Negative Control (375 ng/mL) | 342.4 | 8.86 | **2.45** | 361.7 | 9.24 | **2.55** | 368.6 | 13.24 | **3.59** |
| Cutoff Calibrator (500 ng/mL) | 498.2 | 7.09 | **1.42** | 502.6 | 9.80 | **1.95** | 502.3 | 10.61 | **2.11** |
| Positive Control (625 ng/mL) | 633.5 | 7.76 | **1.22** | 634.8 | 15.25 | **2.40** | 629.7 | 15.32 | **2.43** |

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**Cross Reactivity**

Ecstasy compounds and ecstasy structurally related compounds were tested for cross reactivity. The table below presents representative results for Synchron instruments.

**Ecstasy Compounds That Tested Positive**

| Cross-Reactant | Tested Conc. ng/mL |
|---|---|
| **Cutoff Calibrator 3,4-Methylenedioxymethamphetamine (MDMA)** | **500** |
| 3,4-Methylenedioxyamphetamine (MDA) | 900 |
| 3,4-Methylenedioxyethylamphetamine (MDEA) | 400 |
| N-Methylbenzodioxazolylbutananmine (MBDB) | 2000 |
| Benzodioxazolylbutananmine (BDB) | 1500 |
| p-Methoxyamphetamine (PMA) | 4700 |
| p-Methoxymethamphetamine (PMMA) | 1700 |

**Ecstasy Structurally Related Compounds That Tested Negative**

| Instruments | Synchron CX | UniCel DxC Synchron LX |
|---|---|---|
| **Cross-Reactant Concentration** | **ng/mL** | **ng/mL** |
| **Cutoff Calibrator 3,4-Methylenedioxymethamphetamine (MDMA)** | **500** | **500** |
| d-Amphetamine | 600,000 | 600,000 |
| l-Amphetamine | 10,000 | 30,000 |
| d,l-Amphetamine | 40,000 | 75,000 |
| l-Ephedrine | 800,000 | 800,000 |
| d-Methamphetamine | 200,000 | 300,000 |
| l-Methamphetamine | 10,000 | 10,000 |
| d,l-Methamphetamine | 20,000 | 30,000 |
| Phentermine | 50,000 | 100,000 |
| d,l-Phenylpropanolamine | 800,000 | 800,000 |
| d-Pseudoephedrine | 1,000,000 | 1,000,000 |

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**Method Comparison**

Refer to the Accuracy Section of the Product Insert for GC/MS[c] Comparison

A total of 138 clinical samples were tested in the **Qualitative and Semi-quantitative** modes on the Synchron and compared to the results by GC/MS. The data were analyzed and presented in the table below.

**Qualitative**

| | | CX4 | |
|---|---|---|---|
| | | + | - |
| GC/MS | + | 50 | 0 |
| | - | 7 c | 81 |
| Positive Sample Agreement | | | 100% |
| Negative Sample Agreement | | | 92% |
| Total Sample Agreement | | | 94.9% |

| | | DxC600 | |
|---|---|---|---|
| | | + | - |
| GC/MS | + | 50 | 0 |
| | - | 7 c | 81 |
| Positive Sample Agreement: | | | 100% |
| Negative Sample Agreement | | | 92% |
| Total Sample Agreement | | | 94.9% |

| | | LX20 | |
|---|---|---|---|
| | | + | - |
| GC/MS | + | 50 | 0 |
| | - | 7 c | 81 |
| Positive Sample Agreement: | | | 100% |
| Negative Sample Agreement | | | 92% |
| Total Sample Agreement | | | 94.9% |

**Semi-quantitative:**

| | | CX4 | |
|---|---|---|---|
| | | + | - |
| GC/MS | + | 50 | 0 |
| | - | 7 c | 81 |
| Positive Sample Agreement | | | 100% |
| Negative Sample Agreement | | | 92% |
| Total Sample Agreement | | | 94.9% |

| | | DxC600 | |
|---|---|---|---|
| | | + | - |
| GC/MS | + | 50 | 0 |
| | - | 7 c | 81 |
| Positive Sample Agreement: | | | 100% |
| Negative Sample Agreement | | | 92% |
| Total Sample Agreement | | | 94.9% |

| | | LX20 | |
|---|---|---|---|
| | | + | - |
| GC/MS | + | 50 | 0 |
| | - | 7 c | 81 |
| Positive Sample Agreement: | | | 100% |
| Negative Sample Agreement | | | 92% |
| Total Sample Agreement | | | 94.9% |

c Of the 138 total clinical samples confirmed by GC/MS (Gas Chromatography / Mass Spectrometry) seven were between 500 ng/ml and 634 ng/ml (+25% of cutoff concentration). Due to limitations in sample volume, not all Ecstasy derivatives and/or metabolites were tested for.

## ADDITIONAL INFORMATION

This guideline has undergone limited technical evaluation and is intended to provide guidance only for the use of this reagent on the UniCel® DxC, SYNCHRON LX® and CX® Clinical Systems. The performance characteristics have not been established. You should perform additional testing before reporting diagnostic results.

Information on sample preparation, expected values, quality control, as well as warnings and precautions related to the use of this reagent may be obtained from the package insert.

Instrument operating instructions are contained in the SYNCHRON LX® Operations Manual, SYNCHRON CX® Operating Instructions, or UniCel® DxC Systems Instructions For Use (IFU) Manual.

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

If damaged product is received, notify your Beckman Coulter Clinical Support Center.