

DRI[®] Ecstasy Assay**Kit Configuration**

P/N W15100075	1 x 100 mL Antibody/Substrate Reagent A (R1)
	1 x 100 mL Enzyme Conjugate Reagent E (R2)

Reagent Preparation

P/N W15100075: Reagents are ready to use. Pour R1 and R2 in the appropriate bottles and place them in the reagent tray.

In use Stability

On Board: 30 days

Specimen

Urine

Calibration

Use: Negative Calibrator Cat. No.W151664
 Ecstasy 250 ng/mL Calibrator Cat. No.W15100082
 Ecstasy 500 ng/mL Calibrator Cat. No.W15100081
 Ecstasy 750 ng/mL Calibrator Cat. No.W15100080
 Ecstasy 1000 ng/mL Calibrator Cat. No.W15100079
 Recalibrate every 30 days or when a new lot of reagent is used.

Quality Control

MGC Select DAU Control Set. Cat. No.W15100202 (2 Levels)

Calculation and Analytical Results

The results concentration is automatically calculated by the instrument against the Calibration curve. For detailed description, refer to the Instrument settings and to the ILab 350 Operator Manual.

Semiquantitative results

A rough estimate of drug concentration in the samples can be obtained by running a standard curve with all calibrators and quantitating samples off the standard curve.

References / Literatur / Bibliografia / Bibliographie / Bibliografia /

See package insert inclosed in the kit

Performance Characteristics

The performance below were obtained working with a cutoff of 500 ng/mL

Limitation/Interfering Substances

A positive result by this assay should be confirmed by another nonimmunological method such as GC, TLC or GC/MS.

It is possible that other substances and/or factors (eg, technical or procedural) not listed in the specificity table (see package insert) may interfere with the test and cause false results.

Precision

	Samples/Runs	Mean (ng/mL)	CV(%)	Mean (ng/mL)	CV(%)	Mean (ng/mL)	CV%
Within Run	5/10	387	1.9	499	2.0	640	1.9
Total	5/10	387	2.1	499	2.2	640	2.2

Minimun Detection Limit

18 ng/mL



Instrument Settings

Chemistry Parameters		R1	
Method	<input type="text"/>	Reagent Name	<input type="text" value="EXT"/> Volume <input type="text" value="100 μL"/>
Name	<input type="text" value="EXT"/>	R2	<input type="text" value="enable"/> <input type="text"/>
Unit	<input type="text" value="ng/mL"/>	Reagent Name	<input type="text" value="EXT"/> Volume <input type="text" value="100 μL"/>
Assay Type	<input type="text" value="Rate"/>	Wash	disable Reagent Name <input type="text"/>
			Reagent Type <input type="text"/>
		Diluent	disable Reagent Name <input type="text"/>
Measuring Points	1 disable	start	<input type="text"/>
		end	<input type="text"/>
	2 enable	start	<input type="text" value="15"/>
		end	<input type="text" value="20"/>
Wave Length		Decimal Points	<input type="text" value="0"/>
Prim	<input type="text" value="340"/>	Sec	<input type="text" value="405"/>
		Technical Range (Conc)	<input type="text" value="0 - 1000"/>
		mAbs/10	<input type="text" value="-30000 / 30000"/>
Sampling Volume	<input type="text" value="5 μL"/>	RPT Wash	(R1) <input type="text" value="Sys Water"/>
Dilution	disable		(R2) <input type="text" value="Sys Water"/>
	<input type="text" value="μL"/>		
Rerun (High)	<input type="text" value="μL"/>	Instrument Factor a	<input type="text" value="1"/>
Dilution	disable	Stirring Speed	R1 <input type="text" value="mid"/> R2 <input type="text" value="0"/>
	<input type="text" value="μL"/>		
Rerun (Low)	<input type="text" value="μL"/>		

Calibration Checks

** Duplicate Limit	<input type="text"/>	** mAbs/10	Sampling Method for Standards
** Sensitivity Limit	<input type="text"/>	** mAbs/10	<input type="text"/> Duplicate
			<input checked="" type="checkbox"/> Triplicate
** Linearity Limit	<input type="text"/>	** %	Blank measurement
** Prozone Limit	<input type="text"/>	upper	<input checked="" type="checkbox"/> Disable Reagent blank
SL1-S	**	SL1-F	**
SL2-S	**	SL2-F	**
Sens	<input type="text"/>	mAbs/10	Reagent blank measurement at calibration
			<input type="text"/> Reagent blank (system water)
<input checked="" type="checkbox"/> Absorbance Limit		** Multiplex measurement is the same as standards	Reagent Blank Limit Checks
Reaction	<input type="text" value="Increase"/>		<input type="text"/>
Limit	<input type="text" value="25000"/>	mAbs/10	** Duplicate limit <input type="text" value="50"/> mAbs/10

Calibration

Method	<input type="text"/>	Name	<input type="text" value="EXT"/>	Interval	<input type="text" value="30"/> days
Calculation	<input type="text" value="Point to Point"/>				
	Conc	WORK	MASTER	Lot No	
S1	<input type="text" value="0"/>				K <input type="text" value="N/A"/>
S2	<input type="text" value="250"/>				
S3	<input type="text" value="500"/>				
S4	<input type="text" value="750"/>				
S5	<input type="text" value="1000"/>				
S6	<input type="text"/>				

Reagent Registration

Reagent Code	<input type="text" value="0151"/>				
Reagent Name	<input type="text" value="EXT"/>				
R1	<input checked="" type="checkbox"/> enable	Volume (L)	<input type="text" value="**"/> mL	Volume (S)	<input type="text" value="**"/> mL
R2	<input checked="" type="checkbox"/> enable	Volume (L)	<input type="text" value="**"/> mL	Volume (S)	<input type="text" value="**"/> mL
		Stability Check	<input checked="" type="checkbox"/> enable	Term	<input type="text" value="30"/> days
			<input checked="" type="checkbox"/> enable		<input type="text" value="30"/> days

** Operator definable N/A not applicable to this test