

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

P/N W150017	1 x 100 mL Antibody/Substrate Reagent A (R1)
	1 x 100 mL Enzyme Conjugate Reagent E (R2)

Reagent Preparation

P/N W150017: 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
 MultiDrug Calibrator 1 Cat. No.W151588
 MultiDrug Calibrator 2 Cat. No.W151591
 MultiDrug Calibrator 3 Cat. No.W151594
 MultiDrug Calibrator 4 Cat. No.W151597

Recalibrate every 30 days or when a new lot of reagent is used. Do not run reagent blank with this assay.

Quality Control

MGC Primary DAU Control Set Cat. N°.15100200 (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 600/650 Operator's Manual.

Semiquantitative results

A rough estimate of drug concentration in the samples can be obtained by running a standard curve with all calibrators and quantifying 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 1000 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	729	3.0	1011	2.7	1271	2.5
Total	5/10	729	3.2	1011	2.8	1271	3.2

Minimum Detection Limit

62 ng/mL



Instrument Settings

Photometric Test Parameters		Urine	Ranges and Evaluation Criteria		Urine
Test No.		**	Normal Range-Male		999.9 - 1000
Test Name, Test Code		Amphetamines, Amph	Normal Range-Female		999.9 - 1000
Sample Type		Urine	Normal Range-Other		999.9 - 1000
Reporting Unit, Decimal Points		ng/mL, 0	Valid Range		-100 / 9000
Reaction Cycle		Standard	Hemolysis/Icterus/Lipemia Limit		N/A
Twin Analysis		OFF	Reaction Slope		Positive
Methodology Type, Measuring Point		Rate, 20/25	Absorbance Limit		Above, 3500
Photometric Methodology		2 Wavelength	Prozone Limit		N/A
Primary/Secondary Wavelength		340 / 405	Non Linear Limit		0
Sampling Conditions			Slope/Intercept Correction		1/0
Sampling 1	Sample Vol.	5	Qualitative Report		OFF
	Sample/Diluent Vol.	0/0	Calibration Conditions		
Sampling 2	Sample Vol.	0	Calibration		Multi Point, P to P, 3 Reps
	Sample/Diluent Vol.	0/0	Stability (days)		30
Sampling 3	Sample Vol.	0	Calibrator 1, Concentration		0
	Sample/Diluent Vol.	0/0	Calibrator 2, Concentration		500
Sampling 4		***	Calibrator 3, Concentration		1000
Diluent Code		Saline	Calibrator 4, Concentration		1500
Diluent Warning Limit		N/A	Calibrator 5, Concentration		2000
First Run		Sampling 1	R-Blank Limit (mAbs)		N/A
Below/Above Normal Range		***	Cal. Reps Range (%)		***
Panic L		***	Min Cal. Response (mAbs)		***
Panic H		Sampling 2	Cal. Factor Change (%)		***
Noise		***	M-Point Curve Fit (%)		N/A
Prozone		N/A	Reagent Blank		OFF
High!, ABS!		Sampling 2	Auto R-Blank by Bottle		OFF
Sample Volume Reduction		**	* Lot dependent		
Reagent Volumes			** operator definable		
R1	Code	01411	*** optional		
	Rgt/Dil. Vol. Stirring	100/0, ON	N/A not applicable to this test		
	Low Vol. Warning Limit	20			
	Stability (days)	30			
R2	Code	01412			
	Rgt/Dil. Vol. Stirring	100/0, ON			
	Low Vol. Warning Limit	20			
	Stability (days)	30			