DRI® Benzodiazepine Assay

CE

Kit Configuration

P/N W150039 — 1 x 100 mL Antibody/Substrate Reagent A (R1)
1 x 100 mL Enzyme Conjugate Reagent E (R2)

Reagent Preparation

P/N W150039: 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 3 days or when a new lot of reagent is used.

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 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 quantifying samples off the standard curve.

References / Literatur / Bibliografía / Bibliographie / Bibliografia /

See package insert inclosed in the kit

Performance Characteristics

The performance below were obtained working with a cutoff of 200 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	147	9.1	191	6.4	333	4.8
Total	5/10	147	10.6	191	9.8	333	8.5

Minimun Detection Limit

25 ng/mL

Instrumentation Laboratory
Instrumentation Laboratory SpA – V.le Monza 338 – 20128 Milano (Italy)
Instrumentation Laboratory Company - Lexington, MA 02421-3125 (USA)

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Instrument Settings

Chemistry Parameters				**R1**			
Method				**Reagent Name**	BENZO	**Volume**	100 µL
Name	BENZO			**R2**	enable		
				Reagent Name	BENZO	**Volume**	100 µL
				Wash	disable	**Reagent Name**	
Unit	ng/mL					**Reagent Type**	
Assay Type	Rate			**Diluent**	disable	**Reagent Name**	

Measuring Points	**1** disable	start		**Decimal Points**	0
		end			
	2 enable	start	15	**Normal Range**	199.9 - 200
		end	20		

Wave Lenght							
Prim	340	**Sec**	405	**Technical Range (Conc)**		0 - 1000	
				mAbs/10		-30000 / 30000	
Sampling Volume	5 µL						
Dilution	disable			**RPT Wash**	(R1)	Sys Water	
	µL	µL			(R2)	Sys Water	
Rerun (High)	µL						
Dilution	disable			**Instrument Factor a**	1	**b**	0
	µL	µL		**Stirring Speed**	R1 mid	R2	mid
Rerun (Low)	µL						

Calibration Checks

**	**Duplicate Limit**	**	mAbs/10	**Sampling Method for Standards**	
**	**Sensitivity Limit**	**	mAbs/10		Duplicate
				x	Tripicate
**	**Linearity Limit**	**	%		
				Blank measurement	
**	**Prozone Limit**	** upper		x	Disable Reagent blank
	SL1-S	** SL1-F **		None	
	SL2-S	** SL2-F **		**Reagent blank measurement at calibration**	
	Sens	**	mAbs/10		Reagent blank (system water)
x	**Absorbance Limit**			**	**Multiplex measurement is the same as standards**
	Reaction	Increase			
	Limit	25000	mAbs/10	**Reagent Blank Limit Checks**	
				**	Duplicate limit 50 mAbs/10

Calibration

	Method		**Name**	BENZO	**Interval**	3	**days**
Calculation	Point to Point						

	Conc	WORK	MASTER	Lot No
S1	0			
S2	100			
S3	200			
S4	500			
S5	1000			
S6				

K N/A

Reagent Registration

Reagent Code	0143										
Reagent Name	BENZO										
			Volume (L)			Volume (S)			Stability Check		Term	
R1	x	enable	**	mL		**	mL		x	enable	30	days
R2	x	enable	**	mL		**	mL		x	enable	30	days

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