DRI® Cannabinoid Assay

CE

Kit Configuration

P/N W150185 — 1 x 100 mL Antibody/Substrate Reagent A (R1)
1 x 100 mL Enzyme Conjugate Reagent E (R2)

Reagent Preparation

P/N W150185: 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
THC 20 ng/mL Calibrator Cat. No.W150235
THC 50 ng/mL Calibrator Cat. No.W150042
THC 100 ng/mL Calibrator Cat. No.W150044
THC 200 ng/mL Calibrator Cat. No.W150206
Recalibrate every 30 days or when a new lot of reagent is used.

Quality Control

THC 40 ng/mL Control Cat. No.W150170
THC 60 ng/mL Control Cat. No.W150168
THC 75 ng/mL Control Cat. No.W150214
THC 125 ng/mL Control Cat. No.W150212

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 50 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	32	5.6	45	4.7	63	2.0
Total	5/10	32	9.5	49	6.9	63	2.4

Minimun Detection Limit

1 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**	THC	**Volume**	100 µL
Name	THC			**R2**	enable		
				Reagent Name	THC	**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**	49.9 - 50		
		end	18				
Wave Lenght							
Prim	340	**Sec**	405	**Technical Range (Conc)**	0 - 200		
				mAbs/10	-30000 / 30000		
Sampling Volume	10 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**	
**	**itivity 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**	THC	**Interval**	30	**days**
Calculation	Point to Point					

	Conc	WORK	MASTER	Lot No
S1	0			
S2	20			
S3	50			
S4	100			
S5	200			
S6				

K N/A

Reagent Registration

Reagent Code	0146								
Reagent Name	THC								
			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