DRI® Cotinine Assay

CE

Kit Configuration

P/N W150394	1 x 100 mL Antibody/Substrate Reagent A (R1) 1 x 100 mL Enzyme Conjugate Reagent E (R2)

Reagent Preparation

P/N W1503944: 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: Cotinine Calibrator Cat. No.W150404
Recalibrate every 21 days or when a new lot of reagent is used. Do not run reagent blank with this assay.

Quality Control

Cotinine Low Control Cat. No.W150460
Cotinine High Control Cat. No.W150470

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 / Bibliografía / 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	313	6.7	491	4.2	743	3.9
Total	5/10	313	7.9	491	5.8	743	4.3

Minimun Detection Limit

36 ng/mL

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Instrument Settings

Photometric Test Parameters		***Urine***
Test No.		**
Test Name, Test Code		Cotinine, Coti
Sample Type		Urine
Reporting Unit, Decimal Points		ng/mL, 0
Reation Cycle		Standard
Twin Analysis		OFF
Methodology Type, Measuring Point		Rate, 20/25
Photometric Methodology		2 Wavelenght
Primary/Secondary Wavelenght		340 / 405
Sampling Conditions		
Sampling 1	Sample Vol.	16
	Sample/Diluent Vol.	0/0
Sampling 2	Sample Vol.	0
	Sample/Diluent Vol.	0/0
Sampling 3	Sample Vol.	0
	Sample/Diluent Vol.	0/0
Sampling 4		***
Diluent Code		Water
Diluent Warning Limit		N/A
First Run		Sampling 1
Below/Above Normal Range		***
Panic L		***
Panic H		Sampling 2
Noise		***
Prozone		N/A
High!, ABS!		Sampling 2
Sample Volume Reduction		**
Reagent Volumes		
R1	Code	01541
	Rgt/Dil. Vol. Stirring	100/0, ON
	Low Vol. Warning Limit	20
	Stability (days)	30
R2	Code	01542
	Rgt/Dil. Vol. Stirring	100/0, ON
	Low Vol. Warning Limit	20
	Stability (days)	30

Ranges and Evaluation Criteria	***Urine***
Normal Range-Male	499.9 - 500
Normal Range-Female	499.9 - 500
Normal Range-Other	499.9 - 500
Valid Range	-100 / 9000
Hemolysis/Icterus/Lipemia Limit	N/A
Reaction Slope	Positive
Absorbance Limit	Above, 3500
Prozone Limit	N/A
Non Linear Limit	0
Slope/Intercept Correction	1/0
Qualitative Report	OFF
Calibration Conditions	
Calibration	Multi Point, P to P, 3 Reps
Stability (days)	21
Calibrator 1, Concentration	0
Calibrator 2, Concentration	100
Calibrator 3, Concentration	250
Calibrator 4,Concentration	500
Calibrator 5,Concentration	1000
Calibrator 6,Concentration	2000
R-Blank Limit (mAbs)	N/A
Cal. Reps Range (%)	***
Min Cal. Response (mAbs)	***
Cal. Factor Change (%)	***
M-Point Curve Fit (%)	N/A
Reagent Blank	OFF
Auto R-Blank by Bottle	OFF

*	Lot dependent
**	operator definable
***	optional
N/A	not applicable to this test