

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

P/N W150432	1 x 100 mL Antibody/Substrate Reagent A (R1)
	1 x 100 mL Enzyme Conjugate Reagent E (R2)

Reagent Preparation

P/N W150432: 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: 7 days

Specimen

Urine

Calibration

For qualitative analysis of samples, use:

Negative Calibrator Cat. No.W151664 (0 ng/mL)

MultiDrug Calibrator 2 Cat. No.W151591 (300 ng/mL cut-off)

Recalibrate every 21 days or when a new lot of reagent is used. Do not run reagent blank with this assay.

Data Analysis and results

The ILab calculates the results for this drug of abuse screening test by comparing the sample absorbance with the one obtained for the cut-off calibrator in the prior calibration. Different formats are available on the ILab for the propoxyphene results, depending on the user's choice of some optional parameters. By defining the Upper and Lower Limits of the Normal Range to be equal to the test's cut-off level, the following result's printout formats can be obtained:

Results Printout Format

Test Parameter	Negative Sample	Positive Sample
Qualitative: ON	[-]	[+]
Qualitative: OFF	[concentration] L	[concentration] H

Additionally, the ILab can be set up to report "borderline" results by assigning the Lower Normal Range Limit a lower value (i.e. 80%) than the Upper Limit (cut-off).

Quality Control

MGC Primary DAU Control Set Cat. N°.15100200 (2 levels)

References / Literatur / Bibliografia / Bibliographie / Bibliografia /

See package insert inclosed in the kit

Performance Characteristics**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	Level (ng/mL)	Mean (rate)	CV (%)	Level (ng/mL)	Mean (rate)	CV (%)
Within Run	3/10	252	315	0.6	447	401	0.5
Total	3/10	252	315	0.8	447	401	0.4

Accuracy

Clinical urine samples were assayed in duplicate; results were confirmed by GC/MS

n	Positives	False Positives	Negatives	False Negatives
105	34	0	71	0

Linearity

Not applicable to a screening method such as this one; however ILab system requires that a number be entered as the upper limit of Valid Range.

Sensitivity

milliabsorbance change per 1 ng/mL: 0.43.



Instrument Settings

Photometric Test Parameters		Urine
Test No.		**
Test Name, Test Code		Phropoxyphenr, Prpxy
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 Wavelength
Primary/Secondary Wavelength		340 / 405
Sampling Conditions		
<i>Sampling 1</i>	Sample Vol.	8
	Sample/Diluent Vol.	0/0
<i>Sampling 2</i>	Sample Vol.	0
	Sample/Diluent Vol.	0/0
<i>Sampling 3</i>	Sample Vol.	0
	Sample/Diluent Vol.	0/0
<i>Sampling 4</i>		***
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	01531
	Rgt/Dil. Vol. Stirring	100/0, ON
	Low Vol. Warning Limit	20
	Stability (days)	7
R2	Code	01532
	Rgt/Dil. Vol. Stirring	100/0, ON
	Low Vol. Warning Limit	20
	Stability (days)	7

Ranges and Evaluation Criteria	Urine
Normal Range-Male	299.9 - 300
Normal Range-Female	299.9 - 300
Normal Range-Other	299.9 - 300
Valid Range	-100 7 9000
Hemolysis/Icterus/Lipemia Limit	N/A
Reaction Slope	Positive
Absorbance Limit	Above, 3500
Prozone Limit	N/A
Non Linear Limit	N/A
Slope/Intercept Correction	1/0
Qualitative Report	**
Calibration Conditions	
Calibration	Multi Point, Linear, 3 Reps
Stability (days)	21
Calibrator 1, Concentration	0
Calibrator 2, Concentration	300
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

