

DRI<sup>®</sup> Metaqualone Assay**Kit Configuration**

P/N W150514	1 x 100 mL Antibody/Substrate Reagent A (R1)
	1 x 100 mL Enzyme Conjugate Reagent E (R2)

**Reagent Preparation**

P/N W150514: 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: 21 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 Methaqualone 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	230	235	0.9	462	326	0.5
Total	3/10	230	235	0.9	462	326	0.5

**Accuracy**

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

n	Positives	False Positives	Negatives	False Negatives
92	21	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: 0.39.



### Instrument Settings

<b>Photometric Test Parameters</b>		<b>Urine</b>
Test No.		**
Test Name, Test Code		Methaqualone, Methq
Sample Type		Urine
Reporting Unit, Decimal Points		ng/mL, 0
Reaction Cycle		Standard
Twin Analysis		OFF
Methodology Type, Measuring Point		Rate, 20/25
Photometric Methodology		2 Wavelength
Primary/Secondary Wavelength		340 / 405
<b>Sampling Conditions</b>		
<i>Sampling 1</i>	Sample Vol.	16
	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		**
<b>Reagent Volumes</b>		
R1	Code	01521
	Rgt/Dil. Vol. Stirring	100/0, ON
	Low Vol. Warning Limit	20
	Stability (days)	21
R2	Code	01522
	Rgt/Dil. Vol. Stirring	100/0, ON
	Low Vol. Warning Limit	20
	Stability (days)	21

<b>Ranges and Evaluation Criteria</b>	<b>Urine</b>
Normal Range-Male	299.9 - 300
Normal Range-Female	299.9 - 300
Normal Range-Other	299.9 - 300
Valid Range	-100 / 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	**
<b>Calibration Conditions</b>	
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

