

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

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|-------------|--|
| P/N W150135 | 1 x 100 mL Antibody/Substrate Reagent A (R1) |
| | 1 x 100 mL Enzyme Conjugate Reagent E (R2) |

Reagent Preparation

P/N W150135: 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
 Low Calibrator Cat. No.W150034
 MultiDrug Calibrator 1 Cat. No.W151588
 MultiDrug Calibrator 2 Cat. No.W151591
 MultiDrug Calibrator 3 Cat. No.W151594

Recalibrate every 30 days or when a new lot of reagent is used. Do not run reagent blank with this assay.

Quality Control

MGC Clinical DAU Control Set Cat. N°.15100201 (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 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 / Bibliografia / Bibliographie / Bibliografia /

See package insert inclosed in the kit

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|------------------------------------|
| Performance Characteristics |
|------------------------------------|

The performance below were obtained working with a cutoff of 300 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 | 229 | 2.6 | 311 | 2.7 | 441 | 2.5 |
| Total | 5/10 | 229 | 3.0 | 311 | 3.4 | 441 | 3.4 |

Minimun Detection Limit

10 ng/mL



Instrument Settings

| Photometric Test Parameters | | Urine |
|------------------------------------|------------------------|---------------|
| Test No. | | ** |
| Test Name, Test Code | | Opiate, Op300 |
| 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 |
| Sampling Conditions | | |
| <i>Sampling 1</i> | Sample Vol. | 12 |
| | 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 | 01451 |
| | Rgt/Dil. Vol. Stirring | 100/0, ON |
| | Low Vol. Warning Limit | 20 |
| | Stability (days) | 30 |
| R2 | Code | 01452 |
| | Rgt/Dil. Vol. Stirring | 100/0, ON |
| | Low Vol. Warning Limit | 20 |
| | Stability (days) | 30 |

| 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 / 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) | 30 |
| Calibrator 1, Concentration | 0 |
| Calibrator 2, Concentration | 300 |
| Calibrator 3, Concentration | 1000 |
| Calibrator 4, Concentration | 2000 |
| Calibrator 5, Concentration | 4000 |
| 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

