

DRI[®] Ethyl Alcohol Assay**Kit Configuration**

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|-------------|--|
| P/N W150037 | 1 x 100 mL Antibody/Substrate Reagent A (R1) |
| | 1 x 100 mL Enzyme Conjugate Reagent E (R2) |

Reagent Preparation

P/N W150037: 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: Ethyl Alcohol Negative Calibrator Cat. No.W150311

Ethyl Alcohol 100 mg/dL Calibrator Cat. No.W150241

Recalibrate every 14 days or when a new lot of reagent is used. Do not run reagent blank with this assay.

Quality Control

Ethyl Alcohol 50 mg/dL Control Cat. No.W150239

Ethyl Alcohol 300 mg/dL Control Cat. No.W150243

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

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

The performance below were obtained working with a cutoff of 100 ng/mL

Limitation/Interfering Substances

See Package insert.

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 (mg/dL) | CV(%) | Mean (mg/dL) | CV(%) | Mean (mg/dL) | CV% |
|------------|--------------|--------------|-------|--------------|-------|--------------|-----|
| Within Run | 5/10 | 51 | 1.7 | 99 | 2.4 | 292 | 1.1 |
| Total | 5/10 | 51 | 1.9 | 99 | 2.4 | 292 | 1.1 |

Minimum Detection Limit

1 mg/dL



Instrument Settings

| Photometric Test Parameters | | Urine |
|------------------------------------|------------------------|---------------|
| Test No. | | ** |
| Test Name, Test Code | | EtOH-U, EtOHU |
| Sample Type | | Urine |
| Reporting Unit, Decimal Points | | mg/mL, 0 |
| Reaction Cycle | | Standard |
| Twin Analysis | | OFF |
| Methodology Type, Measuring Point | | Rate, 20/25 |
| Photometric Methodology | | 1 Wavelength |
| Primary/Secondary Wavelength | | 340 |
| Sampling Conditions | | |
| <i>Sampling 1</i> | Sample Vol. | 12 |
| | Sample/Diluent Vol. | 0/0 |
| <i>Sampling 2</i> | Sample Vol. | 6 |
| | Sample/Diluent Vol. | 0/0 |
| <i>Sampling 3</i> | Sample Vol. | 0 |
| | Sample/Diluent Vol. | 0/0 |
| <i>Sampling 4</i> | | *** |
| Diluent Code | | N/A |
| 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 | 01421 |
| | Rgt/Dil. Vol. Stirring | 100/0, ON |
| | Low Vol. Warning Limit | 20 |
| | Stability (days) | 30 |
| R2 | Code | 01422 |
| | Rgt/Dil. Vol. Stirring | 100/0, ON |
| | Low Vol. Warning Limit | 20 |
| | Stability (days) | 30 |

| Ranges and Evaluation Criteria | Urine |
|---------------------------------------|-----------------------------|
| Normal Range-Male | ** |
| Normal Range-Female | ** |
| Normal Range-Other | ** |
| Valid Range | 0 / 500 |
| 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) | 14 |
| Calibrator 1, Concentration | 0 |
| Calibrator 2, Concentration | 100 |
| 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

