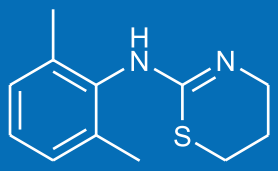
# ARK™ Xylazine Assay




The ARK Xylazine Assay is a homogeneous enzyme immunoassay intended for the qualitative detection and/or semi-quantitative estimation of xylazine and its metabolites in human urine at a cutoff concentration of 10 ng/mL. The assay is intended for use in laboratories with automated clinical chemistry analyzers.


The ARK Xylazine Assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed positive analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/tandem Mass Spectrometry (LC-MS/MS) is the preferred confirmatory method. Confirmatory testing and professional judgment should be exercised with any drug test result, particularly when the preliminary test result is positive.

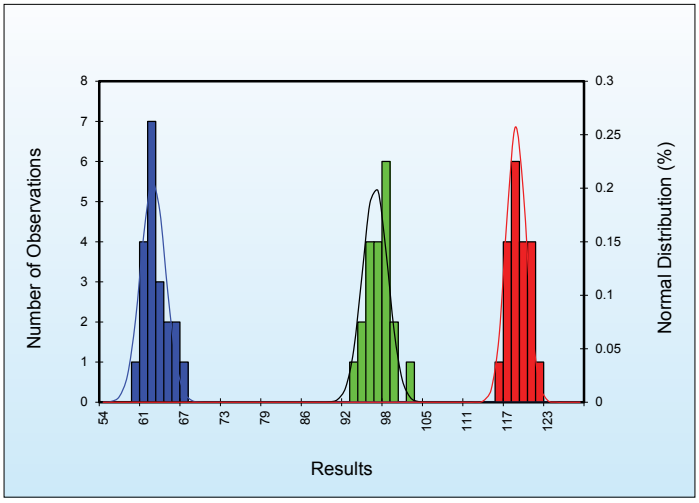
## KEY POINTS

- Convenient, liquid-stable, read-to-use homogeneous enzyme immunoassay
- Applicable onboard automated chemistry analyzers
- 0 – 500 ng/mL semi-quantitative calibration range, 10 ng/mL Cutoff
- High specificity for Xylazine and 4-Hydroxy Xylazine in human urine
- Nonhazardous preservatives

*Next Generation Assays*

ARK Diagnostics, Inc.

## QUALITATIVE PRECISION




Qualitative Control Precision vs 10 ng/mL Cutoff Calibrator

## SEMI-QUANTITATIVE PRECISION

| Human Urine (ng/mL) | Relative % Cutoff | # of Results | Mean (ng/mL) | Semi-quantitative Precision Results |
|---|---|---|---|---|
| 0 | -100 | 160 | 0 | 160 Negative |
| 2.5 | -75 | 160 | 2 | 160 Negative |
| 5.0 | -50 | 160 | 4 | 160 Negative |
| 7.5 | -25 | 160 | 7 | 160 Negative |
| 10.0 | Cutoff | 160 | 10 | 118 Negative / 42 Positive |
| 12.5 | +25 | 160 | 12 | 1 Negative / 159 Positive |
| 15.0 | +50 | 160 | 14 | 160 Positive |
| 17.5 | +75 | 160 | 17 | 160 Positive |
| 20.0 | +100 | 160 | 20 | 160 Positive |

Pooled Urine Samples containing Xylazine were assayed in quadruplicate twice a day for 20 days.

## ACCURACY – ANALYTICAL RECOVERY

| Concentration Tested (ng/mL) | Mean (ng/mL) | Recovery (%) |
|---|---|---|
| 6 | 6 | 96 |
| 9 | 9 | 100 |
| 12 | 12 | 97 |
| 20 | 20 | 101 |
| 60 | 56 | 93 |
| 150 | 134 | 89 |
| 400 | 351 | 88 |

## METHOD COMPARISON

| ARK Xylazine Assay Results | Low Negative <50% of cutoff concentration by LC-MS/MS (< 5.0 ng/mL) | Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration by LC-MS/MS) (5.0 - 9.9 ng/mL) | Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration by LC-MS/MS) (10.0 – 14.9 ng/mL) | High Positive (Greater than 50% above the cutoff concentration by LC-MS/MS) (≥ 15.0 ng/mL) |
|---|---|---|---|---|
| Positive | 0 | 1* | 2 | 30 |
| Negative | 109 | 5 | 0 | 0 |

*One sample with an LC-MS/MS value of 7.4 ng/mL tested positive in the ARK Xylazine Assay.

## CROSS-REACTIVITY

**Metabolites**

| Compound | Concentration Approximately Equivalent to the Cutoff (ng/mL) | Percent Cross-reactivity (%) |
|---|---|---|
| 3-Hydroxy xylazine | 9 | 110 |
| 4-Hydroxy xylazine | 19 | 53 |
| 4-Hydroxy xylazine glucuronide | 38 | 26 |

***α*-2 Agonist and *α*-2 Antagonist Compounds**

| Compound | Concentration Approximately Equivalent to the Cutoff (ng/mL) | Percent Cross-reactivity (%) |
|---|---|---|
| Atipamezole | >100,000 | <0.01 |
| Brimonidine | 15,190 | 0.07 |
| Clonidine | 2,260 | 0.44 |
| Detomidine | >100,000 | <0.01 |
| Dexmedetomidine | >100,000 | <0.01 |
| Etomidate | >100,000 | <0.01 |
| Eutylone | >100,000 | <0.01 |
| Guanfacine | >100,000 | <0.01 |
| Medetomidine | >100,000 | <0.01 |
| Metamizole | >100,000 | <0.01 |
| Romifidine | 2,780 | 0.36 |
| Tizanidine | 9,350 | 0.11 |
| Tolazoline | >100,000 | <0.01 |
| Yohimbine | >100,000 | <0.01 |

**Opiates/Structurally Similar Compounds**

| Compound | Concentration Tested (ng/mL) | Result (POS/NEG) | Percent Cross-reactivity (%) |
|---|---|---|---|
| 6-Acetyl morphine | 100,000 | NEG | <0.01 |
| Buprenorphine | 100,000 | NEG | <0.01 |
| Codeine | 150,000 | NEG | <0.01 |
| Dextromethorphan | 100,000 | NEG | <0.01 |
| EDDP | 100,000 | NEG | <0.01 |
| EMDP | 100,000 | NEG | <0.01 |
| Ethyl morphine | 100,000 | NEG | <0.01 |
| Fentanyl | 100,000 | NEG | <0.01 |
| Heroin | 100,000 | NEG | <0.01 |
| Levorphanol | 100,000 | NEG | <0.01 |
| Meperidine | 100,000 | NEG | <0.01 |
| Methadone | 100,000 | NEG | <0.01 |
| Morphine | 100,000 | NEG | <0.01 |
| Nalbuphine | 100,000 | NEG | <0.01 |
| Naloxegol | 100,000 | NEG | <0.01 |
| Naloxone | 100,000 | NEG | <0.01 |
| Naltrexone | 100,000 | NEG | <0.01 |
| Norbuprenorphine | 100,000 | NEG | <0.01 |
| Norfentanyl | 100,000 | NEG | <0.01 |
| Norcodeine | 100,000 | NEG | <0.01 |
| Normorphine | 100,000 | NEG | <0.01 |
| Noroxycodone | 100,000 | NEG | <0.01 |
| Nortilidine | 100,000 | NEG | <0.01 |
| Oxycodone | 100,000 | NEG | <0.01 |
| Oxymorphone | 100,000 | NEG | <0.01 |
| Pentazocine | 100,000 | NEG | <0.01 |
| Tapentadol | 100,000 | NEG | <0.01 |
| Thebaine | 100,000 | NEG | <0.01 |
| Tilidine | 100,000 | NEG | <0.01 |
| Tramadol | 100,000 | NEG | <0.01 |

## SAFETY AND STABILITY

**Reagent on-board stability**

Up to at least 60 days

**Shelf Life of Reagents, Calibrators, and Controls**

18 months from date of manufacturing

**Safety**

Nonhazardous preservatives
Contains sodium azide ≤ 0.09%

Results shown are typical and may vary among laboratory analyzers.

## ORDERING INFORMATION

**For Criminal Justice and Forensic Use Only within the United States**

| | |
|---|---|
| ARK™ Xylazine Assay<br>(R1 x 28 mL / R2 x 14 mL) | 5088-0001-00 |
| ARK™ Xylazine Assay<br>(R1 x 115 mL / R2 x 58 mL) | 5088-0001-01 |
| ARK™ Xylazine Calibrator<br>(5 x 10 mL) | 5088-0002-00 |
| ARK™ Xylazine Calibrator<br>(2 x 10 mL; Negative) | 5088-0002-01 |
| ARK™ Xylazine Calibrator<br>(2 x 10mL; 10 ng/mL Cutoff) | 5088-0002-02 |
| ARK™ XylazineControls<br>(2 x 10mL; LOW 5 ng/mL)<br>(2 x 10mL; HIGH 15 ng/mL) | 5088-0003-00 |

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MKT24-034 Rev 01 October 2024