# FOR RESEARCH USE ONLY

**UroDetect Drugs of Abuse Panel II - Barbiturate**
**Code: K-ZMC015**
**Revision: 01**

**(P): 508-553-5800**
**(F): 508-520-1525**
**www.zeptometrix.com**

***These reagents are not a substitute for the mandatory positive and negative control reagents provided with licensed test kits.***

## NAME AND INTENDED USE:

The UroDetect Drugs of Abuse Panel II - Barbiturate is intended for use with *in vitro* assay procedures to determine the absence or presence of Barbiturates. This panel is for **Research Use Only** and should not be used in diagnostic procedures.

## SUMMARY:

The UroDetect Drugs of Abuse Panel II - Barbiturate is composed of ten members representing a range of reactivities. Each panel member contains 0.5mL of material prepared from human urine. This panel can be used for training, lot-to-lot comparison of reagent test kits and to evaluate and compare intra laboratory and inter laboratory performance of Barbiturate assays.

## PRINCIPLES OF THE PROCEDURE:

UroDetect reagents have been designed for use with *in vitro* assay procedures for the purpose of monitoring assay performance across a wide range of reactivity levels. UroDetect materials are prepared from processed human urines. Source materials have been processed and treated to eliminate unwanted components and to ensure stability of the final product. The UroDetect Drugs of Abuse Panel II - Barbiturate members should be evaluated as an unknown specimen per the instructions supplied by the manufacturer of the test kit being used.

## REAGENTS:

1. Two vials UroDetect Barbiturate Non-Reactive (0.5mL each).
2. Eight vials UroDetect Barbiturate Reactive (0.5mL each).

## WARNINGS AND PRECAUTIONS:

**FOR *IN VITRO* USE ONLY**

**CAUTION: Handle UroDetect Drugs of Abuse Panel II - Barbiturate reagents and all human based products as if capable of transmitting infectious agents.**

**USE UNIVERSAL PRECAUTIONS**

UroDetect Drugs of Abuse Panel II - Barbiturate reagents are prepared from processed normal human urine. It is recommended that these be handled in accordance with Biosafety Level 2 practices as described in the CDC NIH publication, Biosafety in Microbiological and Biomedical Laboratories (1), or other equivalent guidelines (2,3).

## SAFETY PRECAUTIONS:

1. Clean any spillage immediately and thoroughly using a suitable disinfectant such as 1% bleach solution.
2. Handle and dispose of all specimens, controls and materials used in testing as though they contain infectious agents (1-3).

## HANDLING PRECAUTIONS:

1. Do not use UroDetect Panel reagents beyond the expiration date.
2. Avoid contamination of reagents when opening and sampling.

## STORAGE INSTRUCTIONS:

1. Store UroDetect Panel reagents at 2-8°C when not in use*.
2. Vials should be stored upright to prevent leakage.
3. When stored as directed, UroDetect Panel reagents are suitable for use for up to 60 days after opening.

## INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION:

Alterations in physical appearance may indicate instability or deterioration of UroDetect Panel reagents. Solutions which are visibly turbid should be discarded.

## PROCEDURE:

1. UroDetect Panel reagents may be included in a test run following the procedure provided by the test kit manufacturer for unknown specimens.
2. Allow UroDetect Panel reagents to reach room temperature (15-30°C) prior to use. Return to proper storage after use.
3. Mix contents by gentle swirling prior to use. Do not mix by vigorous shaking, avoid foaming.

## INTERPRETATION OF RESULTS:

UroDetect Panel reagent test results should be determined as recommended for unknown specimens in the package insert for each commercially available test kit.

## LIMITATION OF THE PROCEDURE:

1. UroDetect Panel reagents must not be substituted for the positive and negative control reagents provided with commercially available test kits.
2. UroDetect Panel reagents are provided for **Research Use Only** and must not be used for calibration or as primary reference preparations for any test kit.
3. PROCEDURE and INTERPRETATION OF RESULTS provided in package insert of each commercially available test kit must be followed closely when testing the UroDetect Panel reagents. Deviations from the recommended procedures may produce unreliable results.
4. It is the responsibility of each laboratory to determine the suitability of UroDetect Panel reagents for its particular use. They also must establish guidelines for the interpretation of results.

## SPECIFIC PERFORMANCE CHARACTERISTICS:

The UroDetect Panel reagents were tested using commercially available test systems following the procedures provided by the manufacturer for the testing of unknown specimens. The data contained in this document is intended to be representative of typical test procedures and should be used for informational use only. Each laboratory should establish its own performance characteristics.

- **NOTE: Box and vial labels for this lot indicate the incorrect storage temperature. Please store at 2-8°C when not in use.**

ZeptoMetrix CORPORATION

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## UroDetect Drugs of Abuse Panel II – Barbiturate
## Lot Number: 1112-272-00006

| Panel Member | Amphetamines Ref Range*: 450-550 ng/mL | Barbiturates Ref Range*: 270-330 ng/mL | Benzodiazepine Ref Range*: 270-330 ng/mL | Cannabinoid Ref Range*: 45-55 ng/mL | Cocaine Ref Range*: 125-175 ng/mL | Oxycodone Ref Range*: 0 ng/mL | Methadone Ref Range*: 270-330ng/mL |
|---|---|---|---|---|---|---|---|
| 1 | Negative (<450) | **359 (Pos)** | Negative (<270) | Negative (<45) | Negative (<125) | Negative | **1,324 (Pos)** |
| 2 | Negative (<450) | **547 (Pos)** | Negative (<270) | Negative (<45) | Negative (<125) | Negative | **1,254 (Pos)** |
| 3 | Negative (<450) | **1,632 (Pos)** | Negative (<270) | Negative (<45) | Negative (<125) | Negative | **1,407 (Pos)** |
| 4 | Negative (<450) | **362 (Pos)** | Negative (<270) | Negative (<45) | Negative (<125) | Negative | **1,332 (Pos)** |
| 5 | Negative (<450) | **1,267 (Pos)** | Negative (<270) | **46 (Pos)** | Negative (<125) | Negative | Negative (<270) |
| 6 | Negative (<450) | **340 (Pos)** | Negative (<270) | Negative (<45) | Negative (<125) | **1,227 (Pos)** | **1,248 (Pos)** |
| 7 | Negative (<450) | **1,503 (Pos)** | **3,516 (Pos)** | Negative (<45) | Negative (<125) | Negative | **1,037 (Pos)** |
| 8 | Negative (<450) | **1,396 (Pos)** | Negative (<270) | Negative (<45) | Negative (<125) | Negative | **1,227 (Pos)** |
| 9 | Negative (<450) | Negative (<270) | Negative (<270) | Negative (<45) | Negative (<125) | Negative | Negative (<270) |
| 10 | Negative (<450) | Negative (<270) | Negative (<270) | Negative (<45) | Negative (<125) | Negative | Negative (<270) |

*Expected therapeutic range

This data is intended to be representative of typical test procedures and should be used for informational purposes only.
They are not intended to represent performance specifications.

**REFERENCES:**

1. U.S. Department of Health and Human Services. Biosafety in Microbiological and Biomedical Laboratories. HHS Publication (NIH) 93-8395. Washington: U.S. Government Printing Office, May, 1993.
2. National Committee for Clinical Laboratory Standards. Protection of Laboratory Workers from Infectious Disease Transmitted by Blood, Body Fluids and Tissue – Second Edition, Tentative Guideline. NCCLS Document M29-T2. Villanova, PA: NCCLS, 1991.
3. National Committee for Clinical Laboratory Standards. Clinical Laboratory Waste management; Approved Guideline> NCCLS Document GP 5-A. Villanova, PA: NCCLS, 1993.