DAU – III

(Rapid On-Site Immunoassay Plus TCA Screen)

URINE TOXICOLOGY CONTROL

I. INTENDED USE:

Many analytes can be detected in urine by using analytical test methods. The UTAK DAU – III Control is for use as a quality control material for rapid on-site screening of drugs of abuse in urine. The control material will generate data that checks and evaluates a test method. As a positive control, it is important to have a control material that contains the desired analyte at a value above the desired cut off value so that a continuous quality control program is obtained.

II. SUMMARY AND PRINCIPLES:

Several different techniques are used for evaluating or estimating the variance of results. The three subjects summarized below must be considered with any test method.

1. PREVENTIVE MEASURES:
   These measures are usually contained in the design of the test method and include consideration for reagents, equipment, and operator errors. These measures are designed to minimize variance.
2. QUALITY CONTROL MEASURES:
   When a quality control sample is analyzed at the same time and in the same manner as a patient specimen, an estimate of variance is obtained for the test method. This estimate of variance can be compared to the acceptable limits of variance of the test method.
3. STATISTICAL ANALYSIS OF PATIENT RESULTS:
   As an aid in evaluating overall test results, the past experience of expected results can be compared to the results of any given test run. For example, it would not be expected that all results of a given test run be in an elevated range.

Quality control materials are widely used as a means to aid in the evaluation of test results. The following subjects are to be considered in the use of any control material.

1. Multi-Level — NORMAL / ELEVATED
2. Matrix — HUMAN / ANIMAL / CHEMICAL
3. Availability — SUFFICIENT FOR STATISTICS
4. Form — LIQUID / FROZEN / DRIED
5. Variety — DIFFERENT THAN CALIBRATORS

III. PRODUCT DESCRIPTION:

The matrix for the UTAK DAU – III Control is prepared from normal human urine. The weighed-in concentrations (Target Value) for each analyte are above the cut off values for each lot prepared. Quality control before, during, and after the preparation of the control material insures that each lot is comparable and of the same high quality. The listed values are verified by analytical methods similar to those actually used in a testing laboratory.

IV. PRECAUTIONS:

1. Although the urine donors have been tested and found negative for HBsAg by RIA and HIV by EIA, the control material should be treated as any other potentially infectious agent.
2. For in vitro diagnostic use only.
3. For analytical use only.

V. STORAGE AND STABILITY:

1. Store dried control material at 2-8°C (35-46°F). Stable to expiration date printed on the insert and label.
2. Store reconstituted control material at 2-8°C (35-46°F). **Stable for 30 days after reconstitution**.

VI. PROCEDURE:

1. Remove cap from each vial to be used.
2. Reconstitute control material by adding **exactly 5.0 mL** of **distilled water**, using a **5 mL** volumetric pipette or equivalent.
3. Replace cap and let sit 10-15 minutes.
4. Swirl gently 3-4 minutes to ensure a homogeneous mixture.
5. Swirl gently each time an aliquot is removed to ensure a homogeneous mixture.
6. Assay control material in same manner as patient specimens, following the exact same instructions from the entire test method.
7. Record the results obtained on a quality control chart that describes statistical limits for the test method and the particular lot of control material.

VII. LIMITATIONS:

1. Control material is for use in quality control programs only; it is not intended for use as a calibration standard.
2. Check the lot number on each vial to be sure it corresponds to the lot number printed on the insert.
3. Results are dependent upon proper storage, reconstitution accuracy, and adequate mixing.
4. Control material approximates a patient specimen; it has not been assayed for any analytes not listed in the table below.

VIII. EXPECTED VALUES:

1. Listed in the table below are the Target Value and the *Reference Value.*
2. The *Reference Value* is determined by a one-step immunochromatographic rapid qualitative assay.
3. Laboratories should establish their own values for mean and expected ranges; the mean of several determinations should fall within ±15% of the Target Value.

DAU – III **Lot Number : A4453**
Product # 66813 **Expiration Date : 10/17**

Drug Class	Analyte	Cut Off	Target Value	*Reference Value*
Amphetamines	**d-Methamphetamine**	**1000 ng/mL**	**1400 ng/mL** (9.38 µmol/L)	***Positive***
Barbiturates	**Secobarbital**	**300 ng/mL**	**400 ng/mL** (1.68 µmol/L)	***Positive***
Benzodiazepines	**Oxazepam**	**300 ng/mL**	**400 ng/mL** (1.40 µmol/L)	***Positive***
Cannabinoids	**Delta-9-THC-COOH**	**50 ng/mL**	**75 ng/mL** (0.22 µmol/L)	***Positive***
Cocaine Metabolite	**Benzoylecgonine**	**300 ng/mL**	**400 ng/mL** (1.38 µmol/L)	***Positive***
Methadone	**Methadone**	**300 ng/mL**	**400 ng/mL** (1.29 µmol/L)	***Positive***
Methaqualone	**Methaqualone**	**300 ng/mL**	**400 ng/mL** (1.60 µmol/L)	***Positive***
Opiates	**Morphine**	**300 ng/mL**	**400 ng/mL** (1.40 µmol/L)	***Positive***
Phencyclidine	**Phencyclidine**	**25 ng/mL**	**40 ng/mL** (0.16 µmol/L)	***Positive***
Propoxyphene	**Propoxyphene**	**300 ng/mL**	**400 ng/mL** (1.18 µmol/L)	***Positive***
Tricyclics	**Nortriptyline**	**1000 ng/mL**	**1400 ng/mL** (5.32 µmol/L)	***Positive***

For technical assistance call: UTAK Technical Service (800) 235-3442

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PRODUCT NUMBER:
66813
DFID: LUDOA
5x5ML VIALS, DRIED

EC AUTHORIZED REPRESENTATIVE
EMERGO EUROPE
MOLENSTRAAT 15
2513 BH, THE HAGUE
THE NETHERLANDS

CE