TCA PANEL LEVEL 2
URINE TOXICOLOGY CONTROL

I. INTENDED USE:

Many analytes can be measured in patients by using analytical test methods. The UTAK TCA Panel Level 2 Control is for use as a quality control material for measuring the levels of analytes in urine. It is intended for use on a continuous basis so that a statistical evaluation of testing performance can be 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

The UTAK TCA Panel Level 2 Control is prepared from normal human materials and will generate data that checks and evaluates the results of a test method over the normal and elevated ranges. The principles of statistics require that the same material be available for comparison for any given time period. Dried control materials both extend the usable time period and allow larger quantities to be available. Statistical accuracy requires that a test method be defined for variance and be calibrated with a suitable standard. The quality control materials that are used must be of a sufficient variety so that the measurements and the data that are obtained are independent of the calibration standards. By using a variety of materials, the entire test method can be continuously evaluated to ensure reliable results.

III. PRODUCT DESCRIPTION:

The matrix for the UTAK TCA Panel Level 2 Control is prepared from normal human urine. Every analyte is added and adjusted to the desired concentration range for each lot prepared (Target Value). Quality control before, during, and after the preparation of the control material ensures that each lot is of the same quality.

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 or below 2-8°C (35-46°F). **See table for reconstituted stability.**

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. Control material approximates a patient specimen.

VIII. EXPECTED VALUES:

1. Laboratories should establish their own statistical values for precision and expected ranges.

Lot Number : C2779 **Expiration Date : 04/21**

Analyte	Target Value	Verified Value	Units	Reconstituted Stability (days)
Amitriptyline	400	394	ng/mL	25
Nortriptyline	400	425	ng/mL	25
Amoxapine	400	480	ng/mL	25
Clomipramine	400	373	ng/mL	25
Desmethylclomipramine	400	381	ng/mL	25
Doxepin	400	412	ng/mL	25
Desmethyldoxepin	400	439	ng/mL	25
Fluoxetine	400	402	ng/mL	25
Norfluoxetine	400	383	ng/mL	25
Imipramine	400	393	ng/mL	25
Desipramine	400	408	ng/mL	25
Maprotiline	400	370	ng/mL	25
Mirtazepine	400	380	ng/mL	25
Protriptyline	400	441	ng/mL	25
Trazodone	800	710	ng/mL	25
Trimipramine	400	401	ng/mL	25
Desmethyltrimipramine	400	440	ng/mL	25

UTAK's express and implied warranties (including merchantability and fitness) are conditioned on the observance of UTAK's insert directions with respect to the use of UTAK's products.

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Product Number: 92001
Product Description: TCA Panel Level 2
Lot Number: C2779
Expiration Date: 04/21
Volume: **5x5**mL Vials, LYOPHILIZED

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EC REP

References: CLSI EP05-A2, CLSI EP12-A, CLSI EP14-A2, CLSI EP25-AE, EP17, ISO 13485:2003, ISO 14971:2007