TCA PANEL LEVEL 1
URINE TOXICOLOGY CONTROL

I. INTENDED USE:

Many analytes can be measured in patients by using analytical test methods. The UTAK TCA Panel Level 1 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 1 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 1 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 : C2778 **Expiration Date : 04/21**

Analyte	Target Value	Verified Value	Units	Reconstituted Stability (days)
Amitriptyline	150	151	ng/mL	25
Nortriptyline	150	123	ng/mL	25
Amoxapine	150	150	ng/mL	25
Clomipramine	150	131	ng/mL	25
Desmethylclomipramine	150	119	ng/mL	25
Doxepin	150	139	ng/mL	25
Desmethyldoxepin	150	156	ng/mL	25
Fluoxetine	150	145	ng/mL	25
Norfluoxetine	150	87	ng/mL	25
Imipramine	150	138	ng/mL	25
Desipramine	150	133	ng/mL	25
Maprotiline	150	127	ng/mL	25
Mirtazepine	150	130	ng/mL	25
Protriptyline	150	148	ng/mL	25
Trazodone	300	220	ng/mL	25
Trimipramine	150	131	ng/mL	25
Desmethyltrimipramine	150	140	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: 92000
Product Description: TCA Panel Level 1
Lot Number: C2778
Expiration Date: 04/21
Volume: **5x5**mL Vials, LYOPHILIZED

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