

BI-LEVEL Z DRUGS PLUS URINE TOXICOLOGY CONTROL

I. INTENDED USE:

Many analytes can be measured in patients by using analytical test methods. The UTAK Bi-Level Z Drugs Plus Control is for use as quality control materials for measuring the levels of analytes in urine. All control material 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.

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|-----------------|----------------------------|
| 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 Bi-Level Z Drugs Plus 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 Bi-Level Z Drugs Plus 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:

- 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.
- For in vitro diagnostic use only.
- For analytical use only.

V. STORAGE AND STABILITY:

- Store dried control material at 2-8°C (35-46°F). Stable to expiration date printed on the insert and label.
- Store reconstituted control material at 2-8°C (35-46°F). **Stable for 25 days after reconstitution.**

VI. PROCEDURE:

- Remove cap from each vial to be used.
- Reconstitute control material by adding **exactly 3.0 mL of distilled water**, using a 3 mL volumetric pipette or equivalent.
- Replace cap and let sit 10-15 minutes.
- Swirl gently 3-4 minutes to ensure a homogeneous mixture.
- Swirl gently each time an aliquot is removed to ensure a homogeneous mixture.
- Assay control material in same manner as patient specimens, following the exact same instructions from the entire test method.
- 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:

- Control material is for use in quality control programs only; it is not intended for use as a calibration standard.
- Check the lot number on each vial to be sure it corresponds to the lot number printed on the insert.
- Results are dependent upon proper storage, reconstitution accuracy, and adequate mixing.
- Control material approximates a patient specimen.

VIII. EXPECTED VALUES:

- Listed in the table below are the Target Value and the Reference Value; the Reference Value is derived from replicate analysis performed by independent laboratory testing.
- The Reference Value is determined by High Performance Liquid Chromatography/Tandem Mass Spectrometry (LC-MS/MS), Gas Chromatography/Mass Spectrometry (GC/MS).
- Laboratories should establish their own statistical values for precision and expected ranges; these values should fall within ±15 of the Target Value.

Bi-Level Z Drugs Plus						
Analyte	41500 Z Drugs Plus Level 1			41501 Z Drugs Plus Level 2		
	Lot Number: A9814 Expiration Date: 11/20			Lot Number: A9815 Expiration Date: 11/20		
	Target Value	Reference Value	Units	Target Value	Reference Value	Units
(±)-Baclofen	100	110	ng/mL	300	320	ng/mL
Dextromethorphan	100	120	ng/mL	300	360	ng/mL
Dextrorphan	300	320	ng/mL	600	640	ng/mL
Gabapentin	2000	1900	ng/mL	6000	6000	ng/mL
Ketamine	200	220	ng/mL	600	660	ng/mL
Norketamine	200	200	ng/mL	600	580	ng/mL
Lamotrigine	500	580	ng/mL	1000	1000	ng/ml
Mitragynine*	25	18*	ng/mL	250	187*	ng/mL
Naloxone	100	100	ng/mL	300	310	ng/mL
Naltrexone	100	88	ng/mL	300	260	ng/mL
6-β-Naltrexol	10	10	ng/mL	50	55	ng/mL
Pregabalin	2000	2000	ng/mL	6000	6400	ng/mL
Topiramate	500	530	ng/mL	1000	1000	ng/mL
Zaleplon	5	5.2	ng/mL	50	54	ng/mL
Zopiclone	5	5.5	ng/mL	50	53	ng/mL
Zolpidem	5	6.2	ng/mL	50	60	ng/mL
Zolpidem Phenyl-4-carboxylic acid	5	5.8	ng/mL	50	53	ng/mL

*Mitragynine have been weighed and spiked into this control material but no claim is made for expected values or stability

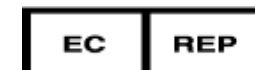
UTAK's express and implied warranties (including merchantability and fitness) are conditioned on the observance of UTAK's insert directions with respect to the use of UTAK's products.

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

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PRODUCT NUMBER:
41500, LEVEL 1
41501, LEVEL 2
5x3ML VIALS, DRIED

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



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