DAU HC 2
URINE TOXICOLOGY CONTROL

I. INTENDED USE:

Many analytes can be measured in patients by using analytical test methods. The UTAK DAU HC 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 DAU HC 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 DAU HC 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). **Stable for 25 days after reconstitution.**

VI. PROCEDURE:

1. Remove cap from each vial to be used.
2. Reconstitute control material by adding exactly 10.0 mL of distilled water, using a 10 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 : C1658 **Expiration Date : 04/21**

Analyte	Target Value	Reference Value	UTAK High Cutoffs	SAMSHA Cutoffs	Units
AMPHETAMINES					
d-Amphetamine	625	644	500	250	ng/mL
d-Methamphetamine	625	587			
MDA	625	553			
MDEA	625	557			
MDMA	625	551			
BARBITURATES					
Amobaribital	375	403	300	N/A	ng/mL
Butalbital	375	422			
Pentobarbital	375	410			
Phenobarbital	375	404			
Secobarbital	375	404			
BENZODIAZEPINES					
α-Hydroxyalprozolam	375	387	300	N/A	ng/mL
Lorazepam	375	392			
Nordiazepam	375	412			
Oxazepam	375	386			
Temazepam	375	379			
CANNABINOIDS					
(I)-Carboxy-11-nor-Delta-9-THC	18.75	22	15	15	ng/mL
COCAINE					
Benzoylecgonine	187.5	186	150	100	ng/mL
METHADONE					
Methadone	375	403	300	N/A	ng/mL
Methadone Primary Metabolite	375	393	300		
METHAQUALONE	375	412	300	N/A	ng/mL
OPIATES					
6-Monoacetylmorphine	12.5	13	10	10	ng/mL
Codeine	2500	2391	2000	2000	
Morphine-3-β-D-Glucuronide	4050* *Equivalent 2500 ng/mL of free morphine	3452.22* *Equivalent to 2131 ng/mL free morhpine	3240* *Equivalent 2000 ng/mL of free morphine	2000	
OPIOIDS					
Hydrocodone	500	476	400	100	ng/mL
Hydromorphone	500	537	400	100	
Oxycodone	375	370	300	100	
Oxymorphone	375	420	300	100	
PHENCYCLIDINE	31.25	33	25	25	ng/mL
PROPOXYPHENE					ng/mL
Norpropoxyphene	375	329	300	N/A	
TRICYCLIC ANTIDEPRESSANTS					ng/mL
Nortriptyline	375	328	300	N/A	

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 (888) 882-5522

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Product Number: 50701
Product Description: DAU HC 2
Lot Number: C1658
Expiration Date: 04/21
Volume: **4x10**mL Vials, Lyophilized

EC Authorized Representative

Emergo Europe

Prinsessegracht 20
2514 AP, The Hague
The Netherlands

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