Validity Check

URINE TOXICOLOGY CONTROL

I. INTENDED USE:

Creatinine, Specific Gravity, and Nitrites can be detected and measured in urine by using analytical test methods. The UTAK Validity Check Control is for use as a quality control material for the identification and confirmation of diluted, substituted, and adulterated urine samples, as defined by the Department of Transportation (DOT) for SAMHSA Certified Laboratories. The control material will generate data that checks and evaluates a test method. In the case of confirmation, it is important to have a control material at or near the desired cut off value.

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 Validity Check Control is prepared from certified drug free human urine containing 0.01% Sodium Azide as a preservative. The concentrations of Creatinine, Specific Gravity, and Nitrite are adjusted to the desired levels 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 were verified by 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 liquid control material at 2-8°C (35-46°F).
2. Stable **unopened** to expiration date printed on the insert and label.
3. **Stable for 30 days after bottle is opened**.

VI. PROCEDURE:

1. Swirl gently 3-4 minutes to ensure a homogeneous mixture.
2. Swirl gently each time an aliquot is removed to ensure a homogeneous mixture.
3. Assay control material in the same manner as patient specimens, following the exact same instructions from the entire test method.
4. Record the results obtained on a quality control chart that describes statistical limits for the test method(s) and the specific lot of quality 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. Laboratories should establish their own values for mean and expected ranges.
4. Results are dependent upon proper storage and adequate mixing.
5. 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 and *Reference Value*; the *Reference Value* are verified by analysis performed by independent laboratory testing.
2. The *Reference Value* are determined by Immunoassay (Olympus AU640E) and by TS Refractometry (Specific Gravity).
3. The mean of several determinations may not duplicate the quantitative values listed below, but should fall within an acceptable range for the specific analytical test method used.

Validity Check

	18010 Low Range		**18011 Mid Range**		**18012 High Range**	
	Lot # : A7691 Exp : 03/20		**Lot # : A7692 Exp : 03/20**		**Lot # : A7693 Exp : 03/20**	
Sample Type	**Substituted**		**Diluted**		**Adulterated**	
Analyte	Target	***Reference Value***	Target	***Reference Value***	Target	***Reference Value***
Creatinine mg/dL	<5	***3.8***	10 - 19	***13.8***	21 - 35	***23.2***
Specific Gravity	≤ 1.001	***1.0009***	≤ 1.003	***1.0022***	> 1.003	***1.0037***
Nitrites µg/mL	Negative	***0***	400	***331***	600	***580***
pH	6 - 7	***6.1***	6 - 7	***6.4***	6 - 7	***6.7***

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

MANUFACTURER:
UTAK LABORATORIES, INC.
25020 AVENUE TIBBITTS
VALENCIA, CA 91355
TEL: (661) 294-3935
FAX: (661) 294-9272
E-MAIL: INQUIRIES@UTAK.COM

PRODUCT NUMBER:
18010, Low Range
18011, Mid Range
18012, High Range
DFID:LIUTE
5x5ML VIALS, LIQUID

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

EC REP

Rev.08/16

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