VALIDITY CONTROLS 1 – 5

ADULTERANT TOXICOLOGY CONTROL

I. INTENDED USE:

The UTAK Validity Controls 1 – 5 are for use as quality control materials that will help identify substituted, diluted, and adulterated urine samples. The control material will generate data that checks and evaluates a test method. In the case of screening, it is important to have a control material that contains the desired analyte at or near the desired cut off value so that a continuous quality control program is 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 — LOW / NORMAL / ELEVATED
2. Matrix — HUMAN / ANIMAL / CHEMICAL
3. Availability — SUFFICIENT FOR STATISTICS
4. Form — LIQUID / FROZEN / DRIED
5. Variety — DIFFERENT THAN CALIBRATORS

The UTAK Validity Controls 1 – 5 will generate data that check and evaluate the results of a test method over the low, normal, and elevated ranges. The principles of statistics require that the same material be available for comparison for any given time period. 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 insure reliable results.

III. PRODUCT DESCRIPTION:

The matrices for UTAK Validity Controls 1 – 5 are prepared from distilled water. The levels of the Adulterants, Creatinine, Specific Gravity, and pH are adjusted to the desired range 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 ranges were verified by analytical methods similar to those actually used in a testing laboratory.

IV. PRECAUTIONS:

1. For in vitro diagnostic use only.
2. For analytical use only.

V. STORAGE AND STABILITY:

1. Store liquid control material at 2-8°C (35-46°F).

VI. PROCEDURE:

1. Swirl gently 3-4 minutes to insure 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 Ranges; each Target Range is verified by analysis performed by independent laboratory testing.
2. 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 CONTROLS

Exp Date: 02/20	**Level 1** Product # 17010 **Lot #: A9218** Target Range	**Level 2** Product # 17011 **Lot #: A9219** Target Range	**Level 3** Product # 17012 **Lot #: A9220** Target Range	**Level 4** Product # 17013 **Lot #: A9221** Target Range	**Level 5** Product # 17014 **Lot #: A9222** Target Range
Chromium VI (µg/mL)	**n/a**	**0**	**n/a**	**n/a**	**>65**
Creatinine (mg/dL)	**n/a**	**1.0 - 1.5**	**3.0 - 4.0**	**21 - 25**	**n/a**
Nitrites (µg/mL)	**500 - 625**	**0**	**200 - 250**	**n/a**	**n/a**
Oxidants (µg/mL)	**n/a**	**0**	**n/a**	**n/a**	**>65**
pH	**4.5 - 9.0**	**3.2 - 4.0**	**10.0 - 10.8**	**4.5 - 5.0**	**11.2 - 12.0**
Specific Gravity	**1.0010-1.0027**	**1.0210 - 1.0250**	**0.9950 - 1.0005**	**1.0040 - 1.0180**	**n/a**

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PRODUCT NUMBER:
17010-17014
DFID: LADOA
1x25ML 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