BI – LEVEL URINE METALS
URINE TOXICOLOGY CONTROL

I. INTENDED USE:

Many metals can be measured or detected in patients by using analytical test methods. The UTAK Bi – Level Urine Metals Control is for use as a quality control material for measuring metal levels 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 result stability, several different techniques are used for evaluating or estimating the variance of results. The three techniques summarized below can be continuously evaluated to ensure reliable results.

Quality control materials are widely used as a means to a general check of the overall quality of testing. Dried control materials both extend the usable time period and are convenient for use in the test method.

III. PRODUCT DESCRIPTION:

The UTAK Bi – Level Urine Metals Control is prepared from normal human urine and will generate data that checks and estimates a patient specimen; it should be treated as any other potentially infectious agent.

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 2-8°C (35-46°F). Stable for 30 days after reconstitution.

VI. PROCEDURE:

1. Remove cap from each vial to be used.

2. Reconstitute control material by adding exactly 5.0 mL of a 1% Hydrochloric Acid Solution, using a 5 mL volumetric pipette or equivalent. Avoid contamination of control material by using metal-free pipettes and dilutors.

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 the 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. Results are dependent upon proper storage, reconstitution accuracy, and adequate mixing.

4. 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 Reference Values; the Reference Value is derived from replicate analysis performed by independent laboratory testing.

2. The Reference Value is determined by Ion Selective Electrode (ISE), Inductively Coupled Plasma / Mass Spectrometry (ICP/MS), Inductively Coupled Plasma / Optical Emission Spectroscopy (ICP/OES), and Colorimetric Method (JAFFE).

3. Laboratories should establish their own mean values; an individual laboratory’s mean of several determinations may not duplicate the values listed below, but should fall within ±15% of the Reference Value.

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Method</th>
<th>12111 Normal Range</th>
<th>12110 High Range</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Reference Value</td>
<td>Reference Value</td>
</tr>
<tr>
<td>Aluminum</td>
<td>ICP/MS</td>
<td>6.3 µg/L (0.23 µmol/L)</td>
<td>32.88 µg/L (1.22 µmol/L)</td>
</tr>
<tr>
<td>Arsenic</td>
<td>ICP/MS</td>
<td>9.12 µg/L (0.12 µmol/L)</td>
<td>94.78 µg/L (1.27 µmol/L)</td>
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<tr>
<td>Cadmium</td>
<td>ICP/MS</td>
<td>0.012 µg/L (0.11 nmol/L)</td>
<td>4.51 µg/L (0.40 nmol/L)</td>
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<tr>
<td>Calcium</td>
<td>ICP/OES</td>
<td>80.3 mg/L (2.0 mmol/L)</td>
<td>488 mg/L (12.2 mmol/L)</td>
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<tr>
<td>Chromium</td>
<td>ICP/MS</td>
<td>2.59 µg/L (49.8 nmol/L)</td>
<td>7.98 µg/L (153.5 nmol/L)</td>
</tr>
<tr>
<td>Cobalt</td>
<td>ICP/MS</td>
<td>0.43 µg/L (7.3 mmol/L)</td>
<td>6.21 µg/L (105.4 mmol/L)</td>
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<tr>
<td>Copper</td>
<td>ICP/MS</td>
<td>24.9 µg/L (0.39 µmol/L)</td>
<td>72.3 µg/L (1.14 µmol/L)</td>
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<tr>
<td>Creatinine</td>
<td>JAFFE</td>
<td>1.16 g/L (10.3 mmol/L)</td>
<td>2.13 g/L (18.8 mmol/L)</td>
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<tr>
<td>Fluoride</td>
<td>ISE</td>
<td>490 µg/L (25.8 µmol/L)</td>
<td>810 µg/L (42.6 µmol/L)</td>
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<tr>
<td>Iron</td>
<td>ICP/OES</td>
<td>50 µg/L (0.90 µmol/L)</td>
<td>430 µg/L (7.7 µmol/L)</td>
</tr>
<tr>
<td>Lead</td>
<td>ICP/MS</td>
<td>0.2 µg/L (0.97 µmol/L)</td>
<td>138.8 µg/L (668.92 µmol/L)</td>
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<tr>
<td>Manganese</td>
<td>ICP/MS</td>
<td>1.46 µg/L (26.6 nmol/L)</td>
<td>2.89 µg/L (52.6 nmol/L)</td>
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<tr>
<td>Mercury</td>
<td>ICP/MS</td>
<td>0.1 µg/L (0.5 mmol/L)</td>
<td>42.48 µg/L (211.78 µmol/L)</td>
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<tr>
<td>Molybdenum</td>
<td>ICP/MS</td>
<td>68.14 µg/L (0.71 µmol/L)</td>
<td>88.64 µg/L (0.92 µmol/L)</td>
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<tr>
<td>Nickel</td>
<td>ICP/MS</td>
<td>5.91 µg/L (100.7 nmol/L)</td>
<td>38.20 µg/L (650.9 mmol/L)</td>
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<tr>
<td>Selenium</td>
<td>ICP/MS</td>
<td>52.36 µg/L (0.66 µmol/L)</td>
<td>69.46 µg/L (0.88 µmol/L)</td>
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<tr>
<td>Vanadium</td>
<td>ICP/MS</td>
<td>0.101 µg/L (2.0 nmol/L)</td>
<td>9.32 µg/L (183.0 mmol/L)</td>
</tr>
<tr>
<td>Zinc</td>
<td>ICP/MS</td>
<td>448.2 µg/L (6.9 µmol/L)</td>
<td>973.4 µg/L (14.9 µmol/L)</td>
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</tbody>
</table>

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 Numbers: 12110, High Range
12111, Normal Range
34ML, VIAL, DRIED

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