BI – LEVEL TRACE ELEMENTS
SERUM TOXICOLOGY CONTROL

I. INTENDED USE:

Many elements can be monitored in patients by using analytical test methods. The UTAK Bi – Level Trace Elements Control is for use as a quality control material for monitoring the accuracy and precision of procedures that measure the levels of trace elements in serum. It is intended for use on a continuous basis so that the deviations of reagents and analytical instrumentation can be detected on a statistical basis.

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 Bi – Level Trace Elements Control is prepared from normal human serum 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. The principle of 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 matrix for the UTAK Bi – Level Trace Elements Control is prepared from normal human serum. The analytes are adjusted to the desired concentration range for each lot prepared. 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 serum has 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 **distilled water**, using a **5 mL** volumetric pipette or equivalent. **Avoid contamination of control material by using metal-free laboratory equipment (pipettes, dilutors, etc.)**
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 PerkinElmer Sciex ELAN DRC II, Inductively Coupled Plasma-Mass Spectrometer.
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 *Expected Range.*

TRACE ELEMENTS

Analyte	Method	66816 Normal Range Lot Number : A8361 Expiration Date : 01/20		66815 High Range Lot Number : A8360 Expiration Date : 01/20	
		Reference Value	***Expected Range***	***Reference Value***	***Expected Range***
Aluminum	**DRC ICP-MS**	**10.9 ng/mL** (0.40 µmol/L)	**6.5 -15.3** (0.24 - 0.56)	**201 ng/mL** (7.45 µmol/L)	**161 - 241** (5.96 - 8.94)
Cadmium	**DRC ICP-MS**	**0.17 ng/mL** (1.51 nmol/L)	**0.13 - 0.21** (1.13 - 1.89)	**9.0 ng/mL** (80.1 nmol/L)	**7.2 - 10.8** (64.1 - 96.1)
Calcium	**DRC ICP-MS**	**8.4 mg/dL** (2.10 mmol/L)	**6.3 - 10.5** (1.58 - 2.63)	**12.7 mg/dL** (3.17 mmol/L)	**10.2- 15.2** (2.54 - 3.80)
Chromium	**DRC ICP-MS**	**0.16 ng/mL** (3.08 nmol/L)	**0.12 - 0.20** (2.31 - 3.85)	**2.27 ng/mL** (43.7 nmol/L)	**1.82 - 2.72** (34.9 - 52.4)
Copper	**DRC ICP-MS**	**1.08 µg/mL** (17.0 µmol/L)	**0.81 - 1.35** (12.8 - 21.3)	**3.06 µg/mL** (48.2 µmol/L)	**2.4 - 3.7** (38.6 - 57.8)
Iron	**DRC ICP-MS**	**62 µg/dL** (11.1 µmol/L)	**46.5 - 77.5** (8.3 - 13.9)	**200 µg/dL** (35.8 µmol/L)	**160 - 240** (28.6 - 43.0)
Magnesium	**DRC ICP-MS**	**16.0 µg/mL** (0.66 mmol/L)	**12.0 - 20.0** (0.50 - 0.83)	**43.0 µg/mL** (1.77 mmol/L)	**34.4 - 51.6** (1.42 - 2.12)
Manganese	**DRC ICP-MS**	**0.47 ng/mL** (8.56 nmol/L)	**0.35 - 0.59** (6.4 -10.7)	**2.51 ng/mL** (45.7 nmol/L)	**2.01 - 3.01** (36.6 - 54.8)
Nickel	**DRC ICP-MS**	**0.4 ng/mL** (6.81 nmol/L)	**0.30 - 0.50** (5.11 - 8.51)	**5.74 ng/mL** (97.8 nmol/L)	**4.6 - 6.9** (78.2 - 117.4)
Selenium	**DRC ICP-MS**	**101 ng/mL** (1.28 µmol/L)	**76 - 126** (0.96 - 1.60)	**281 ng/mL** (3.56 µmol/L)	**225 - 337** (2.85 - 4.27)
Silver	**DRC ICP-MS**	**0.117 ng/mL** (1.08 nmol/L)	**0.09 - 0.15** (0.81 - 1.35)	**10.6 ng/mL** (98.3 nmol/L)	**8.5 - 12.7** (78.6 - 118.0)
Zinc	**DRC ICP-MS**	**0.68 µg/mL** (10.4 µmol/L)	**0.51 - 0.85** (7.80 - 13.0)	**2.64 µg/mL** (40.4 µmol/L)	**2.11 - 3.17** (32.3 - 48.5)

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

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PRODUCT NUMBER:
66815, High Range
66816, Normal Range
DFID:LSTE
5x5ML VIALS, DRIED

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

EC REP

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

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