BLANK SERUM

SERUM TOXICOLOGY CONTROL

I. INTENDED USE:

Blank Serum is intended for use as a suitable matrix for the evaluation of the baseline or matrix response to a test method. In addition, Blank Serum can also be used for the preparation of calibration or control materials in the analysis of many different analytes in plasma and serum.

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 accuracy. 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 the Toxic 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 Blank Serum Control is prepared from normal human materials. 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.

III. PRODUCT DESCRIPTION:

The matrix for the UTAK Blank Serum Control is prepared from normal human serum; the donors have reported to have not ingested prescription drugs or common over the counter preparations prior to donation. 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.
4. Use a clean sampling device each time an aliquot is withdrawn in order to avoid sample contamination.

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.
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 procedure for 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.

VIII. EXPECTED VALUES:

1. Laboratories should establish their own statistical values for precision and expected ranges when used as a matrix for a control.
2. The *Reference Value* is determined by ELISA Technology
3. Laboratories should establish their own assigned values compared to a reference standard, when used as a matrix for a calibrator.

BLANK SERUM **Lot Number : A4939**
Product # 44600 **Expiration Date : 02/18**

	Metric Units				Standard International Units		
Analyte	Cut Off	Target Value	Units	***Reference Value***	Cut Off	Target Value	Units
Amphetamine	**15**	**0**	**ng/mL**	**Negative**	**110.9**	**0**	**nmoL/L**
Benzoylecgonine	**10**	**0**	**ng/mL**	**Negative**	**34.6**	**0**	**nmoL/L**
Methamphetamine	**25**	**0**	**ng/mL**	**Negative**	**167.6**	**0**	**nmoL/L**
Morphine	**5**	**0**	**ng/mL**	**Negative**	**17.5**	**0**	**nmoL/L**
Oxazepam	**25**	**0**	**ng/mL**	**Negative**	**87.2**	**0**	**nmoL/L**
Phencyclidine	**5**	**0**	**ng/mL**	**Negative**	**20.5**	**0**	**nmoL/L**
Secobarbital	**10**	**0**	**ng/mL**	**Negative**	**42**	**0**	**nmoL/L**
Delta-9-THC-COOH	**5**	**0**	**ng/mL**	**Negative**	**14.5**	**0**	**nmoL/L**

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

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PRODUCT NUMBER:
44600
5x5ML VIALS, DRIED

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

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