BI – LEVEL BUSULFAN
PLASMA TOXICOLOGY CONTROL

I. INTENDED USE:
Many analytes can be measured in patients by using analytical test methods. The UTAK Bi – Level Busulfan Control is for use as a quality control material for measuring the levels of busulfan in plasma. 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 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 acceptable limits of variance of the test method.

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 Busulfan Control is prepared from normal human materials 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 used. Dried control materials both extend the usable time period and allow larger quantities to be used. Stable to expiration date printed on the insert.

III. PRODUCT DESCRIPTION:
The matrix for the UTAK Bi – Level Busulfan Control is prepared from normal human defibrinated plasma. The analytes are added and adjusted to the desired concentration range for each lot prepared (Target Value). 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 plasma 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 25 days after reconstitution.

VI. PROCEDURE:
1. Allow fresh frozen control material to thaw at room temperature with cap on.

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