IMMUNOSUPPRESSANTS LEVEL 1 (3 mL)
WHOLE BLOOD TOXICOLOGY CONTROL

I. INTENDED USE:

Many analytes can be measured in patients by using analytical test methods. The UTAK Immunosuppressants Level 1 Control is for use as a quality control material for measuring the levels of immunosuppressive agents in whole blood. 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 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 Immunosuppressants Level 1 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 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. By using a variety of materials, the entire test method can be continuously evaluated to ensure reliable results.

III. PRODUCT DESCRIPTION:

The matrix for the UTAK Immunosuppressants Level 1 Control is prepared from normal human whole blood. 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 whole blood 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). **See table for reconstituted stability**.

VI. PROCEDURE:

1. Remove cap from each vial to be used.
2. Reconstitute control material by adding **exactly 3.0 mL** of **distilled water**, using a **3 mL** volumetric pipette or equivalent.
3. Replace cap and swirl gently by hand 5-10 minutes. **Do not use a rotary or rocker mixer**.
4. **Allow control material to equilibrate for one hour at a room temperature of 18-25ºC (64-77ºF)**. **Continue to swirl gently by hand until a homogeneous mixture is attained**.
5. Mix thoroughly each time an aliquot is removed to ensure a homogeneous mixture.
6. Assay control material (recommended in duplicate) in same manner as patient specimens, following the exact same instructions from the entire test method.
7. Record the results obtained on 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; **for optimal results, minimize control material's exposure to light**.
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 Target Value, the *Reference Value*; the *Reference Value* is derived from replicate analysis performed by independent laboratory testing.
2. The *Reference Value* is determined by High Performance Liquid Chromatography / Tandem Mass Spectrometry.
3. Laboratories should establish their own mean values and ranges

Immunosuppressants Level 1 **Lot Number : A9819**
Product # 41630 **Expiration Date : 10/20**

Analyte	Method	Target Value	*Reference Value*	Units	Reconstituted Stability (days)
Cyclosporine	**LC-MS/MS**	**90**	***91.1***	**ng/mL**	**30**
Everolimus	**LC-MS/MS**	**4**	***4.2***	**ng/mL**	**25**
Sirolimus	**LC-MS/MS**	**4**	***4.2***	**ng/mL**	**25**
Tacrolimus	**LC-MS/MS**	**4**	***4.5***	**ng/mL**	**25**

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 NUMBER:
41630
DFID:LWBTDM
5x3ML VIALS, DRIED

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