

I. INTENDED USE:

Many analytes can be measured in patients by using analytical test methods. The UTAK Immunosuppressants Level 3 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.

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| 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 3 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 3 Control is prepared from normal human whole blood. Every analyte is 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:

- 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.
- For in vitro diagnostic use only.
- For analytical use only.

V. STORAGE AND STABILITY:

- Store dried control material at 2-8°C (35-46°F). Stable to expiration date printed on the insert and label.
- Store reconstituted control material at or below 2-8°C (35-46°F). See table for reconstituted stability.

VI. PROCEDURE:

- Remove cap from each vial to be used.
- Reconstitute control material by adding exactly 3.0 mL of distilled water, using a 3 mL volumetric pipette or equivalent.

- Replace cap and let sit 10-15 minutes.
- Swirl gently 3-4 minutes to ensure a homogeneous mixture.
- Swirl gently each time an aliquot is removed to ensure a homogeneous mixture.
- Assay control material in same manner as patient specimens, following the exact same instructions from the entire test method.
- Record the results obtained on a quality control chart that describes statistical limits for the test method and the particular lot of control material.

VII. LIMITATIONS:

- Control material is for use in quality control programs only; it is not intended for use as a calibration standard.
- Check the lot number on each vial to be sure it corresponds to the lot number printed on the insert.
- Control material approximates a patient specimen.

VIII. EXPECTED VALUES:

- Laboratories should establish their own statistical values for precision and expected ranges.

Lot Number : <u>C2974</u>		Expiration Date : <u>11/21</u>		
Analyte	Target Value	Verified Value	Units	Reconstituted Stability (days)
Cyclosporine	1200	1325	ng/mL	30
Everolimus	25	24.6	ng/mL	25
Sirolimus	25	23.5	ng/mL	25
Tacrolimus	25	23.2	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 (888) 882-5522

UTAK Laboratories, Inc. 25020 Avenue Tibbitts Valencia, CA 91355 T: (888) 882-5522 F: (661) 294-9272 E: welovecontrol@utak.com	Product Number: 41632 Product Description: IMMUNOSUPPRESSANTS LEVEL 3 Lot Number: C2974 Expiration Date: 11/21 Volume: 5x3mL Vials, LYOPHILIZED	EC Authorized Representative Emergo Europe Prinsessegracht 20 2514 AP, The Hague The Netherlands
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