Rap/Tac/CsA CONTROL

For In Vitro Diagnostic Use

INTENDED USE

MORE DIAGNOSTICS' Rap/Tac/CsA CONTROL is intended to be used as a whole blood precision control product for the measurement of rapamycin (sirolimus), tacrolimus and cyclosporine. Tacrolimus, rapamycin and cyclosporine have been assayed for the methods specified on the value sheet. Everolimus has been added as an unassayed analyte.

INTRODUCTION

Rapamycin, tacrolimus and cyclosporine are potent immunosuppressive drugs used primarily in organ transplantation.

The use of controls in clinical chemistry procedures is necessary for the laboratory to obtain consistent and reproducible results. The potential for technical and performance errors is minimized. MORE DIAGNOSTICS' Rap/Tac/CsA Controls provide four meaningful concentrations of rapamycin, tacrolimus and cyclosporine, which can be run side-by-side with the patient sample through all phases of the test assay.

PRODUCT DESCRIPTION

MORE DIAGNOSTICS' Rap/Tac/CsA Controls are prepared from stabilized human whole blood to which rapamycin, tacrolimus and cyclosporine have been added to the appropriate levels. Everolimus has been added as an unassayed analyte. No reconstitution is necessary as the controls are in a frozen form.

Four levels of controls are available. The gravimetric target values are as follows:

ANALYTE	UNITS	LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4
RAPAMYCIN	ng/ml	3	12	24	40
TACROLIMUS	ng/ml	3	7	12	22
CYCLOSPORIN A	ng/ml	80	150	350	750
EVEROLIMUS	ng/ml	3	12	24	40

The gravimetric values are confirmed using LC-MS/MS.
See the accompanying value sheet for lot and method specific values and ranges for rapamycin, tacrolimus and cyclosporine.

PRECAUTIONS

For In Vitro Diagnostics Use

1. Check to see that the lot number on the value sheet corresponds to the lot number on each vial, to ensure correct concentration values.

2. Components of this control that are from human source material have been tested by FDA accepted methods and have been found to be negative/non-reactive for Hepatitis B Surface Antigen (HBsAg), HIV-1, HIV-2, Hepatitis C (HCV), HTLV-

1, and HTLV-2. No known methods can offer total assurance that products derived from human source material will not transmit these diseases. Therefore, products derived from human blood and patient samples should be considered potentially hazardous and handled as if capable of transmitting infectious agents[1].

STORAGE AND STABILITY

FROZEN MATERIAL — MORE DIAGNOSTICS' Rap/Tac/CsA Control is stable until the date indicated on the vial, when stored tightly capped at below –14°C.

THAWED MATERIAL — The thawed control is stable for 45 days after thawing when stored at 2 to 8°C.

CONTAMINATION — If there is visible evidence of microbial growth or gross contamination in the bottle, do not use the material. DISCARD IMMEDIATELY!

PROCEDURE

1. Remove vial from freezer and allow to warm to room temperature, 18 - 28˚C.

2. Thoroughly mix by repeated gentle inversion of the vial prior to each sampling. Remove the amount required for the test procedure. **DO NOT CAUSE FOAMING!**

3. Tightly recap the vial immediately after sampling.

4. Treat the control sample in the same manner as the patient sample, as specified in the assay procedure.

5. Store thawed control at 2 - 8˚C.

6. Repeat steps 2 through 5 for resampling. **IT IS NOT NECESSARY TO WARM THE CONTROL PRIOR TO RESAMPLING!**

LIMITATIONS

This product is to be used as a control material and is not intended to be used for calibration.

MORE DIAGNOSTICS' Rap/Tac/CsA Control has been evaluated for those methods specified on the value sheet.

Each lot of control has its own determined value and values may vary between lots.

The means and ranges for rapamycin, cyclosporine and tacrolimus indicated on the VALUE SHEET were obtained from replicate analyses. The value sheet should be used a guideline, as individual laboratories may not obtain the mean values for the constituents as listed for each lot. Techniques, equipment differences, reagent changes and experimental error may produce slightly different values, however the values should fall within the expected range. Each laboratory should determine its own mean values and acceptable ranges for this product.

LOT AND METHOD SPECIFIC EXPECTED VALUES

SEE ACCOMPANYING VALUE SHEET

REFERENCES

1. "Biosafety in Microbiological and Biomedical Laboratories", Centers for Disease Control and Prevention and National Institutes of Health, 1993.

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ORDERING INFORMATION

Packaged in single level boxes	Cat. No.	285-1	6 X 5 ml vials
	Cat. No.	285-2	6 X 5 ml vials
	Cat. No.	285-3	6 X 5 ml vials
	Cat. No.	285-4	6 X 5 ml vials
Packaged in 4-level boxes	Cat. No.	285	4 X 5 ml vials