

DIAGNOSTICS



Your Key To Reliable Quality Controls

CERTIFICATE OF ANALYSIS

MATERIAL Rap/Tac/CsA CONTROL CATALOG NUMBER 290 LOT NUMBER 6019
STORAGE LONG TERM STORAGE = < -14°C USE = 2 TO 8°C
OUTDATE 2020/01/18 **MANUFACTURE DATE** =
INTENDED USE For In Vitro Diagnostic Use LEVEL 1 2016/03/09
 LEVEL 2 2016/03/15
 LEVEL 3 2016/03/16

PRECAUTION ALL INGREDIENTS DERIVED FROM HUMAN SOURCE MATERIAL HAVE BEEN TESTED AND FOUND NEGATIVE FOR HEPATITIS B SURFACE ANTIGEN, HIV-1 & HIV-2 ANTIBODIES AND HEPATITIS C VIRUS ANTIBODIES. CERTIFICATES OF ANALYSIS FROM VENDORS ON FILE.

<u>SPECIFICATIONS</u>	<u>SPIKED TO LEVEL¹</u>	<u>LC-MS/MS RECOVERY</u> MEAN/SD	<u>THAWED STABILITY²</u>
LEVEL 1, LOT 60191			
<u>THAWED VALUES</u>			
Tacrolimus	4.5 ng/mL	4.4/0.4ng/mL	PASSES SOP A107
Cyclosporine	80ng/mL	75.5/6.3ng/mL	PASSES SOP A107
Rapamycin/Sirolimus	4.5ng/mL	4.5/0.3ng/mL	PASSES SOP A107
LEVEL 2, LOT 60192			
<u>THAWED VALUES</u>			
Tacrolimus	11ng/mL	11.2/0.9ng/mL	PASSES SOP A107
Cyclosporine	200ng/mL	192/14.2ng/mL	PASSES SOP A107
Rapamycin/Sirolimus	11ng/mL	11.0/0.9ng/mL	PASSES SOP A107
LEVEL 3, LOT 60193			
<u>THAWED VALUES</u>			
Tacrolimus	22ng/mL	22.3/1.5ng/mL	PASSES SOP A107
Cyclosporine	350ng/mL	331.1/32.3ng/mL	PASSES SOP A107
Rapamycin/Sirolimus	22ng/mL	20.9/1.8ng/mL	PASSES SOP A107

1 - Gravimetrically determined.

2 - When stored between 2 - 8°C the thawed stability should be at least 45 days when determined as per SOP A107.

QC VERIFICATION P. Bernal
 RA VERIFICATION AR Holden

DATE 11-18-16
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DATA ON MORE, \DATA\QA\C_of_A290\CofA_6019R1.pdf
 Rev. No. One 11/18/16