

DIAGNOSTICS



Your Key To Reliable Quality Controls

CERTIFICATE OF ANALYSIS

Material: Rap/Tac/CsA CONTROL	Catalog Number: 290	Lot Number: 7310	
Long Term Storage: < -14°C		Short Term Storage: 2-8°C	
Outdate: 2021/11/05	Manufacture Date (Level 1): 2017/11/07	Manufacture Date (Level 2): 2017/11/08	Manufacture Date (Level 3): 2017/11/09

Intended Use: For In-Vitro Diagnostic Use

SPECIFICATIONS	SPIKED TO LEVEL ¹	LC-MS/MS RECOVERY MEAN/SD	THAWED STABILITY ²
LEVEL 1, LOT: 73101			
THAWED VALUES			
Tacrolimus	4.5 ng/mL	4.7/0.2 ng/mL	PASSES SOP A107
Cyclosporine	80 ng/mL	87/6 ng/mL	PASSES SOP A107
Rapamycin/Sirolimus	4.5 ng/mL	5.1/0.4 ng/mL	PASSES SOP A107
LEVEL 2, LOT: 73102			
THAWED VALUES			
Tacrolimus	11 ng/mL	11.3/0.6 ng/mL	PASSES SOP A107
Cyclosporine	200 ng/mL	216/16 ng/mL	PASSES SOP A107
Rapamycin/Sirolimus	11 ng/mL	12.4/0.9 ng/mL	PASSES SOP A107
LEVEL 3, LOT: 73103			
THAWED VALUES			
Tacrolimus	22 ng/mL	20.5/0.9 ng/mL	PASSES SOP A107
Cyclosporine	350 ng/mL	379/24 ng/mL	PASSES SOP A107
Rapamycin/Sirolimus	22 ng/mL	22.4/1.5 ng/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: <i>Azita Berni</i>	Date: 4-16-17
RA Verification: <i>Harry Holden</i>	Date: 4-16-18

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