

DIAGNOSTICS

Your Key To Reliable Quality Controls

CERTIFICATE of ANALYSIS

Material: Rap/Tac/CsA		Catalog Number: 280		Lot Number: 8057	
Long Term Storage: 2 years @ < -14°C			Short Term Storage: 30 days @ 2-8°C		
Outdate: 2020-02-26		Manufacture Date: 02-26-2018		Intended Use: In Vitro Diagnostic Use	
SPECIFICATIONS	SPIKED TO LEVEL¹	RECOVERY	THAWED STABILITY²		
LEVEL 1, LOT:					
THAWED VALUES					
Tacrolimus (QMS)	4.5 ng/mL	\bar{x} 4.3 ng/mL SD 0.5	PASSES SOP A121		
Cyclosporine (CEDIA)	80 ng/mL	\bar{x} 77.2 ng/mL SD 8.5	PASSES SOP A121		
Rapamycin	4.5 ng/mL	ng/mL	UNASSAYED		
LEVEL 2, LOT:					
THAWED VALUES					
Tacrolimus (QMS)	11 ng/mL	\bar{x} 9.4 ng/mL SD 0.6	PASSES SOP A121		
Cyclosporine (CEDIA)	200 ng/mL	\bar{x} 205.0 ng/mL SD 29.1	PASSES SOP A121		
Rapamycin	11 ng/mL	ng/mL	UNASSAYED		
LEVEL 3, LOT:					
THAWED VALUES					
Tacrolimus (QMS)	22 ng/mL	\bar{x} 19.2 ng/mL SD 1.0	PASSES SOP A121		
Cyclosporine (CEDIA)	350 ng/mL	\bar{x} 356.6 ng/mL SD 32.3	PASSES SOP A121		
Rapamycin	22 ng/mL	ng/mL	UNASSAYED		
Microbial Load: < 10 CFU/mL or Passes SOP A121					
Fill Volume: Mean = \geq 4.1mL as measured Gravimetrically.					
1- Gravimetrically Measured.					
2- When stored between 2-8°C the thawed stability should be at least 30 days when determined as per SOP A121.					
QC VERIFICATION: <i>Emily Cowl</i>			DATE: 7-5-18		
RA VERIFICATION: <i>Harry Holden</i>			DATE: 7-5-18		
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 Antibodies, Hepatitis C Virus Antibodies (HCV), HTLV-1 & HTLV-2 Antibodies, Chagas Disease, West Nile Virus and Syphilis. 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. Certificates of analysis from vendors are on file.					