DIAGNOSTICS

Your Key To Reliable Quality Controls

CERTIFICATE of ANALYSIS

Material: Rap/Tac/CsA	**Catalog Number:** 280	**Lot Number:** 7172
Long Term Storage: 2 years @ < -14°C	**Short Term Storage:** 30 days @ 2-8°C	
Outdate: 2019-06-21	**Manufacture Date: 06-21-2017**	**Intended Use:** In Vitro Diagnostic Use

SPECIFICATIONS	SPIKED TO LEVEL[1]	RECOVERY	THAWED STABILITY[2]
LEVEL 1, LOT: 71721			
THAWED VALUES			
Tacrolimus (QMS)	4.5 ng/mL	$\bar{x}$ 3.9 ng/mL SD 0.3	**PASSES SOP A121**
Cyclosporine (CEDIA)	80 ng/mL	$\bar{x}$ 65.6 ng/mL SD 11.2	**PASSES SOP A121**
Rapamycin	4.5 ng/mL	ng/mL	**UNASSAYED**
LEVEL 2, LOT: 71722			
THAWED VALUES			
Tacrolimus (QMS)	11 ng/mL	$\bar{x}$ 10.0 ng/mL SD 0.5	**PASSES SOP A121**
Cyclosporine (CEDIA)	200 ng/mL	$\bar{x}$ 183.2 ng/mL SD 15.3	**PASSES SOP A121**
Rapamycin	11 ng/mL	ng/mL	**UNASSAYED**
LEVEL 3, LOT: 71723			
THAWED VALUES			
Tacrolimus (QMS)	22 ng/mL	$\bar{x}$ 19.5 ng/mL SD 1.0	**PASSES SOP A121**
Cyclosporine (CEDIA)	350 ng/mL	$\bar{x}$ 333.6 ng/mL SD 18.2	**PASSES SOP A121**
Rapamycin	22 ng/mL	ng/mL	**UNASSAYED**

Microbial Load: < 10 CFU/mL or Passes SOP A121

Fill Volume: Mean = ≥ 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:	Ajka Gernad	**DATE:**	9-29-17
RA VERIFICATION:	HR Holden	**DATE:**	9-29-17

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, 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.