

DIAGNOSTICS

Your Key To Reliable Quality Controls

CERTIFICATE of ANALYSIS

Material: Mycophenolic Acid		Catalog Number: 240		Lot Number: 8129	
Long Term Storage: 3 years @ <-14°C			Short Term Storage: 45 days @ 2-8°C		
Outdate: 2021-05-08		Manufacture Date: 2018-05-09		Intended Use: In Vitro Diagnostic Use	
SPECIFICATIONS	ACCEPTABLE RANGE	RECOVERY¹	THAWED STABILITY²		
LEVEL 1, LOT:					
THAWED VALUES					
MPA (LC-MS/MS)	1-3 µg/mL	1.68 µg/mL	PASSES SOP A107		
LEVEL 2, LOT:					
THAWED VALUES					
MPA (LC-MS/MS)	6-9 µg/mL	6.67 µg/mL	PASSES SOP A107		
LEVEL 3, LOT:					
THAWED VALUES					
MPA (LC-MS/MS)	10-14 µg/mL	10.78 µg/mL	PASSES SOP A107		
LEVEL 4, LOT:					
THAWED VALUES					
MPA (LC-MS/MS)	17.6-26.4 µg/mL	20.94 µg/mL	PASSES SOP A107		
Microbial Load: < 10 CFU/mL or Passes SOP A107					
Fill Volume: Mean = ≥ 2.0mL as measured Gravimetrically.					
1- Recovery by LC-MS/MS. For EMIT 2000 and DIM MPAT recovery see Value Sheet.					
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>Emily Camb</i>		DATE: 7-24-2018			
RA VERIFICATION: <i>Harry R Holsten</i>		DATE: 7-24-2018			
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.					