

DIAGNOSTICS



Your Key To Reliable Quality Controls

CERTIFICATE OF ANALYSIS

MATERIAL CYCLOSPORINE C2 CONTROL

CATALOG NUMBER 202

LOT NUMBER 7338

STORAGE LONG TERM STORAGE = <-14°C USE = 2 TO 8°C

OUTDATE = 2021-12-03 **MANUFACTURE DATE** = 2017-12-04

INTENDED USE For In Vitro Diagnostic Use

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 LEVEL*</u>	<u>METHOD</u>	<u>RESULTS</u> MEAN/SD
LEVEL 1, LOT 73381 <u>VALUES</u> Cyclosporine	600 ng/mL	EMIT® 2000 Cyclosporine for C2 Monitoring	634.5/60.2 ng/mL
LEVEL 2, LOT 73382 <u>VALUES</u> Cyclosporine	1200 ng/mL	EMIT® 2000 Cyclosporine for C2 Monitoring	1319.4/107.1 ng/mL
LEVEL 3, LOT 73383 <u>VALUES</u> Cyclosporine	1800 ng/mL	EMIT® 2000 Cyclosporine for C2 Monitoring	1716.5/158.1 ng/mL

QC VERIFICATION Jate Bernad DATE 5-14-18

RA VERIFICATION Harry Holden DATE 5-17-18

* = Gravimetrically determined.

DATA ON MORE, \QA\C_of_A\202\CofA_7388

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