CMV DNA AccuTrak™ Qualification Panel

2400-0201 / Batch # 10174098

OVERVIEW

The CMV DNA AccuTrak™ Qualification Panel (2400-0201) is a 9 member panel with established reactivity in Cytomegalovirus (CMV) DNA assays (1 vial per member, 2.0 mL per vial). The panel consists of seven members formulated by diluting cultured CMV into CMV DNA negative plasma, one negative member prepared from the CMV DNA negative plasma, and one vial of diluent, also prepared from CMV DNA negative plasma, to perform additional dilutions as desired. Sodium azide (0.09%) was added as a preservative.

Test results from leading CMV DNA assays are included for characterization of the panel members. Results are reported for each panel member on each specific test method.

For Research Use Only. Not for use in diagnostic procedures. Data are provided for informational purposes. SeraCare Life Sciences does not claim that others can duplicate test results exactly.

CAUTION: These materials have not been treated and should be considered biohazardous. Follow Universal Precautions.

CMV DNA

Panel Member	Panel Member ID	SeraCare Batch #	Roche COBAS® AmpliPrep/COBAS® TaqMan® CMV Test log IU/mL[1]	Simplexa™ CMV Kit log copies/mL[2]
01	2400-0211	10174091	**6.22**	**5.97**
02	2400-0212	10174093	**3.99**	**4.05**
03	2400-0213	10174089	**8.32**[3]	**>6.30**
04	2400-0214	10174094	**3.22**	**2.98**
05	2400-0215	10174095	**2.54**	<2.30
06	2400-0216	10174090	**7.41**[3]	**>6.30**
07	2400-0217	10174096	TND	<2.30
08	2400-0218	10174092	**5.15**	**4.73**
09 (Diluent)	2400-0219	10174097	TND	<2.30
Test Date			17-Mar-2016, 29-Mar-16	23-Mar-2016
Test Site			RL	RL
Test Kit Range			150 to 10,000,000 copies/mL 137 to 9,100,000 IU/mL	200 to 2,000,000 copies/mL
Test Kit Conversion Factor			1 copy/mL = 0.91 IU/mL, 1 IU/mL = 1.1 copies/mL	NA
Kit Part Code			NA	NA
Kit Lot No.			W1138300000	NA
Kit Regulatory Status			IVD, CE	RUO

[1]Results are reported as the mean result of triplicate testing. Results in red are considered positive.
[2]Panel members were run in singlicate. Results in red are considered positive.
[3]Panel members were tested at a 1:100 dilution and results were corrected for the dilution factor.
[4]Panel members were tested at both 1:10 and 1:100 dilutions, results were corrected for the dilution factor, and the average was calculated.
TND = Target Not Detected
RL = Reference Lab; NA = Not Available; IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking; RUO = Research Use Only

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The package insert for this panel can be found at www.seracare.com

A printed copy of the package insert or data sheet may be requested by email at info@seracare.com or by phone at 508.244.6400