AccuTrak™ HCV RNA Genotype Qualification Panel

2400-0182 / Batch #10337969

OVERVIEW

AccuTrak™ HCV RNA Genotype Qualification Panel (2400-0182) is a 9-member validation panel with established reactivity for Hepatitis C (HCV) Genotype assays (1 vial per member, 1.2 mL per vial). The eight positive panel members were formulated by diluting HCV RNA positive plasma samples from eight different genotypes into HCV RNA negative plasma. The negative member was formulated from HCV RNA negative plasma. Sodium azide (0.09%) was added as a preservative.

Test results from commercially available HCV Genotype assays are included for characterization of the panel members. This panel demonstrates a range of HCV genotypes. Concentration data are also included from a commercially available HCV RNA assay.

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. The potential for transmission of infectious agents exists, and these materials should be handled following good laboratory safety practice.

HCV Genotype and HCV RNA

Panel Member	Panel Member ID	SeraCare Batch #	Siemens VERSANT® HCV Genotype 2.0 (LiPA)	GenMark Dx eSensor® HCVg Direct Test	Roche COBAS® AmpliPrep/COBAS® TaqMan® HCV Quantitative Test, v2.0 (IU/mL)[1,2]
01	2400-0183	10337959	1A	1A	**7.7×10^4**
02	2400-0184	10337960	1B	1B	**3.6×10^4**
03	2400-0185	10337961	2A/2C	2A/2C	**1.0×10^5**
04	2400-0186	10337962	2B	2B	**2.3×10^4**
05	2400-0187	10337963	3A	3	**2.1×10^4**
06	2400-0188	10337964	4	4	**2.9×10^4**
07	2400-0189	10337965	5A	5	**1.1×10^5**
08	2400-0190	10337967	6c*	6	**5.3×10^4**
09	2400-0191	10337968	NA	NA	TND
Test Date			30-Mar-2018, *04-May-2018	30-Mar-2018	14-Jun-2018
Test Site			RL	RL	RL
Kit Part Code			NA	NA	NA
Kit Lot No.			NA	NA	NA
Kit Exp. Date			NA	NA	NA
Kit Regulatory Status			IVD	RUO	IVD/CE

[1]Results are reported as the mean result of duplicate testing.
[2]Results are reported as International Units per mL (IU/mL); positive/reactive results are noted in bold red.
NA = Not Available; TND = Target Not Detected;
RL = Reference Lab;
IVD = In Vitro Diagnostic; RUO = Research Use Only;
CE = Conformité Européenne or CE Marking

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.