AccuTrak™ HCV RNA Genotype Qualification Panel

2400-0182 / Batch 10389793

OVERVIEW

AccuTrak™ HCV RNA Genotype Qualification Panel 2400-0182 / Batch 10389793 is a 9-member validation panel with established reactivity for Hepatitis C (HCV) Genotype assays (1 vial per member, 1.2 mL per vial), representing eight different HCV genotypes. The eight positive panel members were formulated by diluting with 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. HCV RNA quantitative 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.

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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	2400-0182-01	10389784	1A	1A	**4.2×10^4**
02	2400-0182-02	10389785	1B	1B	**1.8×10^4**
03	2400-0182-03	10389786	2A/2C	2A/2C	**3.8×10^4**
04	2400-0182-04	10389787	2B	2B	**1.7×10^4**
05	2400-0182-05	10389788	3A	3	**1.8×10^4**
06	2400-0182-06	10408956	4ACD	4	**5.2×10^4**
07	2400-0182-07	10389790	5A	5	**4.3×10^4**
08	2400-0182-08	10389791	6C	6	**2.2×10^4**
09	2400-0182 Neg Diluent	10389792	N/A	N/A	TND
Test Dates			11-Dec-2018 04-Apr-2019	12-Dec-2018 04-Apr-2019	06-Mar-2019 14-Mar-2019 23-Apr-2019
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.
N/A = Not Applicable; 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.