

AccuTrak™ HCV RNA Genotype Qualification Panel

2400-0182 / Batch #10527727

OVERVIEW

AccuTrak™ HCV RNA Genotype Qualification Panel 2400-0182 / Batch #10527727 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	10527718	1A	1A	(4.66 x 10⁴)
02	2400-0184	10527719	1B	1B	(2.57 x 10⁴)
03	2400-0185	10527720	2A/2C	2A/2C	(1.85 x 10⁴)
04	2400-0186	10527721	2B	2B	(3.16 x 10⁴)
05	2400-0187	10527722	3A	3	(2.85 x 10⁴)
06	2400-0188	10527723	4A/C/D	4	(1.13 x 10⁵)
07	2400-0189	10527724	5A	5	(3.21 x 10⁴)
08	2400-0190	10527725	6	6	(3.24 x 10⁴)
09	2400-0191	10527726	UTG	UTG	TND
Test Dates			13-Oct-2020 29-Oct-2020 30-Oct-2020	14-Oct-2020 29-Oct-2020	21-Dec-2020 05-Jan-2021 02-Feb-2021
Test Site			RL	RL	RL
Kit Part Code			NA	NA	NA
Kit Lot No.			NA	53676985	G04623, G16918
Kit Exp. Date			NA	21-Jul-2021	31-Aug-2021, 30-Sep-2021

¹Results are reported as the mean result of triplicate testing.

²Results are reported as International Units per mL (IU/mL); positive/reactive results are noted in bold red.

NA = Not Available; TND = Target Not Detected; UTG = Unable to Genotype, RL = Reference Lab

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.