

AccuTrak™ HCV RNA Genotype Qualification Panel

2400-0182 / Batch #10658625

OVERVIEW

AccuTrak™ HCV RNA Genotype Qualification Panel 2400-0182 / Batch #10658625 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 offered for informational purposes. LGC SeraCare Life Sciences does not claim that others can duplicate test results exactly.

CAUTION: Potentially infectious materials. Follow Universal Precautions. Some panel members were found positive for HCV RNA; all were found negative for anti-HIV-1/2 and HBsAg. This does not ensure the absence of these or other human pathogens.

Panel Member Information

Panel Member	Panel Member ID	SeraCare Batch #	Siemens VERSANT® HCV Genotype 2.0 (LiPA) ¹	GenMark Dx eSensor® HCVg Direct Test ¹	Roche COBAS® AmpliPrep/COBAS® TaqMan® HCV Test, v2.0 (IU/mL) ²
01	2400-0183	10658613	1A	1A	3.32 x 10⁴
02	2400-0184	10658615	1B	1B	2.70 x 10⁴
03	2400-0185	10658616	2	2A/C	9.31 x 10⁴
04	2400-0186	10658619	2	2B	4.56 x 10⁴
05	2400-0187	10658620	3	3	2.04 x 10⁴
06	2400-0188	10658621	4	4	4.33 x 10⁴
07	2400-0189	10658622	5	5	2.05 x 10⁴
08	2400-0190	10658623	6	6	2.53 x 10⁴
09	2400-0191	10658624	NA	NA	TND
Test Date			03-Feb-2023 05-Feb-2023 07-Feb-2023	02-Feb-2023	05-Apr-2023
Test Site			RL	RL	RL
Kit Part Code			NA	NA	NA
Kit Lot No.			NA	380967	J18949
Kit Exp. Date			NA	02-May-2024	31-Oct-2023

¹Results are reported as singlicate testing.

²Results are reported as the mean result of duplicate testing;
Positive/reactive results are noted in bold red.

RL = Reference Lab; NA = Not Available; TND = Target Not Detected

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 CDx-Info@LGCGroup.com or by phone at 508.244.6400.