

# HCV RNA Genotype AccuTrak™

## Qualification Panel

2400-0182 / Batch # 10164558

### OVERVIEW

The HCV RNA Genotype AccuTrak™ Qualification Panel (2400-0182) is a nine (9) member panel with established reactivity in 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.

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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	Roche COBAS® AmpliPrep/COBAS® TaqMan® HCV v2.0 (IU/mL) <sup>1</sup>
01	2400-0183	10164547	1a	1a	1.28 x 10 <sup>5</sup>
02	2400-0184	10164549	1b	1b	1.07 x 10 <sup>5</sup>
03	2400-0185	10164550	2a/c	2a/c	1.85 x 10 <sup>5</sup>
04	2400-0186	10164551	2b	2b	5.14 x 10 <sup>4</sup>
05	2400-0187	10164552	3a	3	5.73 x 10 <sup>4</sup>
06	2400-0188	10164553	4a	4	1.62 x 10 <sup>4</sup>
07	2400-0189	10164554	5a	5	7.06 x 10 <sup>4</sup>
08	2400-0190	10164555	6	6	1.79 x 10 <sup>5</sup>
09	2400-0191	10164556	NA	NA	TND
Test Date			9-Feb-2016/3-Mar-2016	11-Feb-2016	2-Mar-2016
Test Site			RL	RL	RL
Kit Part Code			NA	NA	NA
Kit Lot No.			NA	51969743	NA
Kit Conversion Factor			NA	NA	1 IU/mL = 2.7 copies/mL
Kit Regulatory Status			RUO	RUO	IVD, CE

<sup>1</sup>Results are reported as the mean result of duplicate testing

TND = Target Not Detected; RL = Reference Laboratory; NA = Not Available; RUO = Research Use Only; IVD = In Vitro Diagnostic  
CE = Conformité Européenne or CE Marking

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The package insert for this panel can be found at [www.seracare.com](http://www.seracare.com)

A printed copy of the package insert or data sheet may be requested by email at [info@seracare.com](mailto:info@seracare.com) or by phone at 508.244.6400

#### ASK ABOUT

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- HCV RNA AccuSpan™ Linearity Panel
- Disease State Biological Materials
- ACCURUN® Independent Quality Controls
- SeraCon™ and Basematrix Processed Plasma