

# AccuTrak™ HBV DNA Genotype Qualification Panel

2400-0225 / Batch #10614214

## OVERVIEW

AccuTrak™ HBV DNA Qualification Panel 2400-0225 / Batch #10614214 is a 9-member validation panel with established reactivity for Hepatitis B (HBV) Genotype assays (1 vial per member, 1.2 mL per vial). The eight positive panel members were formulated by diluting HBV DNA positive plasma samples from various genotypes into HBV DNA negative plasma. The negative member was formulated from HBV DNA negative plasma. Sodium azide (0.09%) was added as a preservative.

Test results from commercially-available HBV Genotype assays are included for characterization of the panel members. This panel demonstrates a range of HBV genotypes. Concentration data are also included from a commercially-available HBV DNA 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 HBV DNA; all were found negative for anti-HIV-1/2 and anti-HCV. This does not ensure the absence of these or other human pathogens.

## HBV Genotype and HBV DNA

Panel Member	Panel Member ID	SeraCare Batch #	HBV Genotype <sup>1</sup>	Roche cobas® 6800/8800 HBV DNA (IU/mL) <sup>2</sup>
01	2400-0226	10614188	A	<b>4.55 x 10<sup>4</sup></b>
02	2400-0227	10614190	B	<b>9.44 x 10<sup>4</sup></b>
03	2400-0228	10614191	C	<b>2.02 x 10<sup>5</sup></b>
04	2400-0229	10614194	D	<b>6.70 x 10<sup>4</sup></b>
05	2400-0230	10614197	E	<b>5.28 x 10<sup>4</sup></b>
06	2400-0231	10614203	F	<b>9.74 x 10<sup>4</sup></b>
07	2400-0232	10614207	C	<b>2.06 x 10<sup>5</sup></b>
08	2400-0233	10614208	*H	<b>3.28 x 10<sup>3</sup></b>
09	2400-0234	10614212	N/A	TND
Test Date			14-Apr-2022 *04-Jun-2022	13-Jul-2022 14-Jul-2022
Test Site			RL	RL
Kit Part Code			NA	NA
Kit Lot No.			NA	NA
Kit Exp. Date			NA	NA

<sup>1</sup>Genotypes were classified at regional reference labs using commercially available HBV Genotype methods.

<sup>2</sup>Results 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](http://www.seracare.com).

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