



LABORATORY UPDATE

January 20th, 2020

TEST CHANGE NOTIFICATION

Dear Physicians and Staff,

Effective January 20th 2020, Enzo Clinical Laboratory will replace the Roche COBAS® AmpliPrep/TaqMan® HBV, v2.0 Test with a new test method, the Enzo AMPIPROBE® HBV Test. The differences between the current and new HBV DNA viral load tests are summarized below:

	NEW	CURRENT
TEST NAME	AMPIPROBE HBV DNA	COBAS AmpliPrep/TaqMan HBV,v2.0
TEST CODE	6489	5314
REFERENCE RANGE	Not Detected	< 20 IU/mL
REPORTABLE RANGE	20 - 100,000,000 IU/mL (1.30 - 8.00 Log10 IU/mL)	20 - 170,000,000 IU/mL (1.30- 8.20 Log10 IU/mL)
SPECIMEN REQUIREMENTS	Serum/Plasma	Serum/Plasma
TURN AROUND TIME	5 days	5 days

The AMPIPROBE HBV DNA Quant PCR is a real-time PCR assay for the quantitative detection of the Hepatitis B virus DNA in human EDTA-plasma or serum of HBV-infected individuals. This test is intended for use as an aid in the management of patients with chronic HBV infection by measuring HBV DNA levels at baseline and during treatment to assess response to treatment. It is not intended for use in the screening of blood, plasma, or tissue donors for HBV, or as a diagnostic test to confirm the presence of HBV infection. Results from this test must be interpreted within the context of all relevant clinical and laboratory findings.

If you have any questions and/or concerns, please feel free to contact us at 631-755-5500 or reach out to your local sales or service representative.

We appreciate the continued opportunity to serve you and your patients!

Sincerely,

Dieter Schapfel, MD
Medical Director

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