

Laboratory Update

March 17, 2025

Potential false negative result with Roche Cobas Hepatitis B Quantitative real-time PCR

REVISED 19 MAR 2025

DMC University Laboratories has received a notification from Roche Diagnostic regarding possible false negative results given by their cobas® real time quantitative Hepatitis B PCR assay. The internal root cause investigation by Roche has determined that the false negative results could happen on rare occasions due to a problem with the mathematical formula used in the interpretation of test results. The vendor has resolved the issue by updating the software.

Our laboratory has always used a delta check comparing the PCR result with the serology results. Given the delta check policy, the chance for false negative Hepatitis B PCR result reported by our laboratory is minimal. If a report of undetectable HBV DNA incompatible with other diagnostic tests such as serology markers and/or ALT/AST liver injury enzymes is noted, **the HBV PCR test should be repeated.**

Please note that the cobas® hepatitis B DNA PCR assay was implemented at DMC University Laboratories on March 26, 2024 and the result of samples tested prior to this date were not affected by this problem.

For questions or inquiries, please contact:

PCR laboratory: (313) 993-7098

Fadi Gammou, Microbiology manager: (313) 745-2134

Dr. H. Salimnia, Technical Director: (313) 745-2130

Dr. Timothy Kennedy, CLIA Medical Director: (313) 745-4571

DMC University Laboratories

4201 St. Antoine • Detroit, MI 48201 • 313-745-4100 / 1-800-456-2154

www.dmc.ul.org