

# bioMONTR Labs

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## bioMONTR Labs Announces New Assay for Hepatitis B Pregenomic RNA Quantitation

RESEARCH TRIANGLE PARK, N.C., April 8, 2019

(NewsWire.com) - bioMONTR Labs is pleased to announce that we have completed the analytical validation of our new assay for the detection and quantitation of Hepatitis B

pregenomic RNA in chronic HBV (CHB) patients. This first-of-

its-kind HBV pgRNA Research Use Only (RUO) assay utilizes automated extraction, and proprietary, specially designed oligos, and real-time PCR for HBV pgRNA quantitation. The results of our analytical validation study will be presented at the ASM sponsored 2019 Clinical Virology Symposium in Savannah, Georgia.



Recent studies indicate HBV pgRNA may be a useful clinical biomarker in evaluating CHB patient response to treatment with nucleos(t)ide analogues (NA). NA treatment suppresses viral replication by blocking HBV DNA synthesis but does not affect transcription of HBV pgRNA. Further, it has been proposed that pgRNA serves as a surrogate marker for cccDNA and provides a direct assessment of infection status during treatment of CHB without the need for liver biopsies. This automated method provides reproducible results from patient plasma or serum with high sensitivity and specificity. Results from testing CHB patient samples suggest that this high-throughput RUO method will allow the evaluation of HBV pgRNA in patients on NA treatment as a clinical biomarker in drug development studies.

“bioMONTR Labs is pleased to present the results of this validation study,” said Daniel McClernon, President and CSO of bioMONTR Labs. “I am immensely proud of this milestone. We expect that the detection of pgRNA will be an important biomarker utilized in new drug development for chronic HBV patients.”

### About bioMONTR Labs

bioMONTR Labs is a privately owned, CLIA Certified lab located in Research Triangle Park, North Carolina. The company offers a comprehensive menu of high-complexity, molecular-based assays, as well as other proprietary and esoteric testing. For more information on the company, its management, test menu and capabilities, please visit [www.biomontr.com](http://www.biomontr.com).

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Source: bioMONTR Labs