

bioMONTR® is pleased to announce that we have expanded our test menu to include a host of novel HBV biomarkers that can be utilized to guide new drug development towards improving management of people living with chronic hepatitis B.



With the current lack of predictive markers available to guide treatment decisions for chronic hepatitis B (CHB) patients, novel HBV biomarkers are in development to improve patient outcomes. bioMONTR Labs is dedicated to supporting these on-going initiatives and has expanded our test menu to include a range of novel HBV biomarkers utilizing molecular and serological assays. We continue to work closely with leading diagnostic companies to provide CLIA certified high-complexity laboratory services and we stand ready to support your HBV testing needs. Contact bioMONTR Labs to discuss including these novel biomarkers in your drug development studies to monitor CHB patient response, viral activity and disease progression.

bioMONTR Labs HBV Test Menu includes:

- Abbott m2000 RealTime HBV pgRNA¹
- Abbott m2000 RealTime HDV RNA²
- Abbott m2000 RealTime HBV DNA
- ARCHITECT HBsAg/anti-HBs Immune Complex
- ARCHITECT HBsAg Isoforms
- ARCHITECT HBcAg^{3,4}
- ARCHITECT qHBeAg
- ARCHITECT qHBsAg
- ARCHITECT anti-HDV²

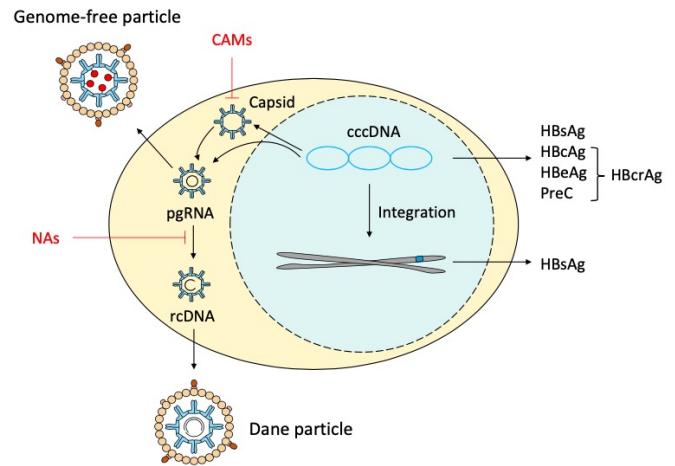


Figure 1: Schematic presentation of non-HBV DNA- and HBV DNA-containing (Dane particles) particle synthesis in CHB patients and mode of action of action of nucleotide analogs (NAs) and capsid assembly modulators/inhibitors (CAMs).³

- Results from testing CHB patient samples suggest that this high-throughput method will allow evaluation of HBV pgRNA in patients on NA treatment as a clinical biomarker in drug development studies.¹
- Prototype serologic and molecular tests provide sensitive and specific methods for HDV detection using high throughput automated platforms, allowing opportunity for improved diagnosis of HDV infected patients.²
- The ability to specifically distinguish between the various states of HBcAg (phosphorylated and non-phosphorylated) provides additional insights for disease staging, drug development, and management of HBV therapies.^{3,4}
- bioMONTR Labs is a CLIA certified high complexity diagnostic laboratory (ID # 34D2049579) offering tests across a wide range of therapeutic areas.

Contact us via our website <http://www.bioMONTR.com> or at 919-650-1185 for more information regarding these assays

References:

1. Anderson M, Stec M, Thi E, Picchio G, Mbanya D, Cloherty G. "Measuring hepatitis B pgRNA stability using an updated automated HBV pgRNA assay with increased sensitivity." *Hepatology Communications*, 2023;7:e0099.
2. Coller K, Butler E, Luk K, Rodgers M, Cassidy M, Gersch J, McNamara A, Kuhns M, Dawson G, Kaptue L, Bremer B, Wedemeyer H, Cloherty G. "Development and performance of prototype serologic and molecular tests for hepatitis delta infection." *Scientific Reports*, 8, 2095 (2018).
3. Geissler R, Patel M, Anderson M, Vaillant A, Qui X, Cloherty G. "Development and Clinical Utility of High-throughput HBcAg-specific Immunoassays for the Management of HBV Therapies." *APASL Annual Meeting*, February 2023.
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