MICHIGAN MEDICINE
UNIVERSITY OF MICHIGAN
LABORATORIES

Test update 869

Posted Date 02/14/2024
Effective Date 02/14/2024
Test Name Hepatitis B Virus DNA by PCR, Quantitative
Update Type Test Methodology Changed
CPT Code 87517

TEST PLATFORM UPDATE

Hepatitis B Virus DNA by PCR, Quantitative

Order Code: QHBV

Fee Code: 32371 (CPT 87517)

The Michigan Medicine Clinical Microbiology Laboratory has switched from the Abbott M2000 to the Abbott Alinity platform for Hepatitis B Virus DNA by PCR, Quantitative, testing effective February 14, 2024. This switch is being made because the M2000 platform is reaching end of life and provides:

- More frequent testing via use of random-access instrument.
- Demonstrated clinical utility of viral load <2000 IU/ml or >2 log decrease in viral load.
- High sensitivity (10 IU/mL)
- High precision:
  - Standard deviation (SD): ≤ 0.25 Log IU/mL from 2 to 9 Log IU/mL (100 to 1,000,000,000 IU/mL)
  - Standard deviation (SD): ≤ 0.35 Log IU/mL near the Lower Limit of Quantification (10 to 30 IU/mL)

Note that on average, values on the new Assay (Alinity) are 0.6 log10 IU/mL (4-fold) higher than the old assay. For example, a result of 2000 IU/mL (3.3 log10) on the old assay will be approximately 8,000 IU/mL (log 3.9 log10) on the new assay. However, there is a tight linear relationship between the old and new assays, and we observe very similar trends in serial patient results over time in both assays. To enable re-baselining of patient values, for approximately the next one-month transition period, any quantified results on the new assay will be repeated on the old assay and reported as a test comment. The average bias will also be included as a comment for the next 12 months.

The new assay is designed to detect differences of at least 5-fold (0.7 log10) IU/mL between samples. There is also biological variation to consider. In the clinical trial, the within-subject SD in *untreated patients* was 0.72 log10 IU/mL between consecutive values 12 weeks apart.

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