ACL Laboratories Test Bulletin

Effective February 15, 2012

ACL Laboratories updates assay reportable ranges for monitoring HCV, HBV and CMV viral loads

ACL Laboratories is updating the methods used for detection, quantification and reporting of HCV, HBV and CMV viral loads (Test Order Codes: HCVQTM, HBVQTM and CMVQN, respectively).

Current viral load monitoring was based on real-time RT-PCR **ASR reagents** from Abbott Molecular. The new reagents also are from Abbott, but **U.S. FDA approved** and provide greater sensitivity, and a broader dynamic range.

- For HCV detection and quantification (Test Order Code: HCVQTM), the new linear range of the assay is 12-100,000,000 IU/ml or 1.08-8.00 log10 IU/ml of plasma or serum. Limit of Detection (LOD) is 12 IU/ml.
- For HBV detection and quantification (Test Order Code: HBVQTM), the new linear range of the assay is 10-1,000,000,000 or 1.00-9.00 log10 IU/ml of plasma. Limit of Detection (LOD) is 10 IU/ml.

To comply with an accrediting agency requirement of the College of American Pathologists, ACL Laboratories is introducing new reporting units for CMV quantitative viral load assay (Test Order Code: CMVQN).

Current CMVQN unit "copies/mL" is being replaced by international unit IU/mL. International units are traceable to CMV DNA WHO International Standard (NIBSC 09/162) and conversion factor is 1 IU/mL = 1.72 copies/mL. New converted range of the assay is 150-6,000,000 IU/ml or 2.18-6.78 log 10 IU/ml. Limit of Detection (LOD) is 150 IU/ml.

ACL validation studies indicate equivalence between ASR and IVD Abbott reagents for both HCV and HBV. No conversion or re-baselining is necessary.

Medicare, other payers implement frequency limitations on hemoglobin A1c testing

Hemoglobin A1c (or glycated hemoglobin/protein) testing is widely accepted as medically necessary for the management and control of diabetes. Testing is also valuable to assess hyperglycemia, a history of hyperglycemia or dangerous hypoglycemia.

Medicare policy considers this testing to be reasonable and necessary ***every three months*** on a controlled diabetic patient capable of maintaining long-term, stable metabolic control. Medicare also considers the testing to be reasonable and necessary once a month on diabetic pregnant women.

Hemoglobin A1c testing ***will not be reimbursed more frequently than once every three months*** without documentation that the patient's condition requires testing more frequently. More frequent hemoglobin A1c assessment may be appropriate for patients requiring a change in diabetes regimen to improve metabolic control or patients who have experienced a major event that may have altered metabolic control.

Note that the Medicare three-month count begins ***the day after the date of service*** for the billed test. For example, if the patient presents December 15, 2011, for a hemoglobin A1c test (ACL Test Order Code: GLYH), another test will not be eligible for Medicare reimbursement until March 16, 2012, unless conditions documenting the need for more frequent testing are provided.

Unless more frequent testing is required ***and documented*** for patient care, please allow a full three months between hemoglobin A1c tests. Patients arriving for testing at ACL locations within three months of their previous visit will be asked to sign an Advance Beneficiary Notice of Noncoverage and will be held financially responsible for any fees denied by insurance.

Please refer to the ACL Laboratories Directory of Services (acllaboratories.com/tests-directory/search-tests.asp) for specimen collection requirements.

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