DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Centers for Disease Control
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Lawrence A Baker, Ph.D.
Principal Staff Scientist
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Dear Dr. Baker:

Thank you for your assistance in providing us samples and test result information to include in our evaluation of the optimal screening-test-positive signal-to-cut-off (s/co) for predicting a confirmed anti-HCV result when using the Bayer ADVIA anti-HCV assay (CIA – Chemiluminescent Enzyme Immunoassay). The relationship between s/co ratios and RIBA 3.0 results was evaluated for specimens that were screening-test-positive by CIA (i.e., reactive by Bayer ADVIA anti-HCV) from two groups; one group with a low prevalence (range 2 – 5% - persons in the general population, health care workers, and consecutive CIA anti-HCV positives from Kaiser North HMO), and one with a high prevalence (range ≥ 12.5% - hemophiliacs, dialysis patients, persons identified with high risk sexual behavior, patients with signs and symptoms, transfusion/transplant recipients and injection drug users). For both groups, an s/co ratio of ≥11 predicted RIBA positivity in 97% or more of the screening-test-positive samples. Although the sample sizes were smaller than those used for our original evaluation of other FDA-approved assays, the 95% confidence intervals surrounding the point estimates indicate that the point estimates were not significantly different for these groups.

These results indicate that for the FDA-approved Bayer ADVIA CIA, reflex supplemental testing of screening-test-positive samples can be limited to those with s/co ratios <11. When screening test positive results with s/co ratios ≥11 are reported without confirmation, we recommend including the type of explanatory comments suggested in our published laboratory guidelines. These guidelines, if adopted by laboratories that perform in vitro diagnostic anti-HCV testing, will improve the accuracy and utility of reported anti-HCV results for counseling and medical evaluation of patients by health-care professionals and for surveillance by public health departments. Thank you again for your support.

Sincerely,

W. Kuhnert

Wendi L. Kuhnert, Ph.D.
Division of Viral Hepatitis
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