DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC

1600 Clifton Road, MS A33
Atlanta, Georgia 30333
404-371-5900
404-371-5435 (fax)

May 24, 2007

Mary C. Kuhns, Ph.D.
Infectious Diseases Scientific Affairs
Abbott Diagnostics
100 Abbott Park Road
Dept. 9C9, Bldg. AP20
Abbott Park, IL 60064

Dear Dr. Kuhns:

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 Abbott Architect anti-HCV assay (CMIA – Chemiluminescent Microparticle Immunoassay). The relationship between s/co ratios and RIBA 3.0 results was evaluated for specimens that were screening-test-positive by CMIA (i.e., reactive by Abbott Architect anti-HCV) from two groups; one group with a low prevalence (range 2 – 5% - persons in the general population, health care workers, and consecutive CMIA anti-HCV positives from LabCorp), and one with a high prevalence (range ≥ 18% - persons with identified risk factors and persons exhibiting signs and symptoms of viral hepatitis). For both groups, an s/co ratio of ≥5 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 Abbott Architect CMIA, reflex supplemental testing of screening-test-positive samples can be limited to those with s/co ratios <5. When screening test positive results with s/co ratios ≥5 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
National Center for HIV/AIDS, Viral Hepatitis,
STD, and TB Prevention