



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)

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Dr. Mark R. Sanborn, Ph.D.
Manager, Global Scientific Affairs
Abbott Diagnostic Division
Abbott Laboratories
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Dear Dr. Sanborn:

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 AxSYM® anti-HCV assay (MEIA – Microparticle Enzyme Immunoassay). The relationship between s/co ratios and RIBA 3.0 results was evaluated for specimens that were screening-test-positive by MEIA (i.e., reactive by Abbott AxSYM® anti-HCV) from two groups; one group with a low prevalence (range 2 – 5% - persons in the general population, random hospitalized patients, and consecutive MEIA anti-HCV positives from LabCorp), and one with a high prevalence (range $\geq 64\%$ - hemophiliacs and injection drug users). For both groups, an s/co ratio of ≥ 10 predicted RIBA positivity in 97% or more of the screening-test-positive samples. Although the sample sizes of these two groups were smaller than those used for our original evaluation of other FDA-approved assays, the 95% confidence intervals surrounding the point estimates were similar.

These results indicate that for the FDA-approved MEIA, reflex supplemental testing of screening-test-positive samples can be limited to those with s/co ratios < 10 . When screening test positive results with s/co ratios ≥ 10 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,

Miriam J. Alter, Ph.D.
Associate Director for Epidemiologic Science
Division of Viral Hepatitis
National Center for Infectious Diseases