Submission Date: 05/19/05

Committee: Infectious Disease
05-ID-11

Title: Revision of the Criteria for Laboratory Diagnosis of Hepatitis C Virus Infection, Chronic or Resolved (2002)

Statement of the Problem:
The laboratory criteria for diagnosis in the 2002 Case Definition defines anti-HCV positivity by signal to cut-off ratio(≥3.8) only for the EIA . Since that time anti-HCV test methodologies other than the EIA have been validated, and are in common use. These tests have different signal to cut-off rations predictive of a true positive. The current case definition would not permit these test results to be used to confirm laboratory positivity.

Statement of the desired action(s) to be taken:
Revise the Laboratory criteria for diagnosis, as follows:

ORIGINAL
Laboratory criteria for diagnosis
Anti-HCV positive (repeat reactive) by EIA, verified by an additional more specific assay
(e.g. RIBA for anti-HCV or nucleic acid testing for HCV RNA)
or
Anti-HCV positive (repeat reactive) by EIA with a signal to cut-off ratio ≥3.8.

REVISED
Laboratory criteria for diagnosis
Anti-HCV positive (repeat reactive) by EIA, verified by an additional more specific assay (e.g. RIBA for anti-HCV or nucleic acid testing for HCV RNA),
OR
HCV RIBA positive,
OR
Nucleic acid test for HCV RNA positive,
OR
Report of HCV genotype
OR
Anti-HCV screening-test-positive with a signal to cut-off ratio predictive of a true positive as determined for the particular assay (e.g., ≥3.8 for the enzyme immunoassays) as determined and posted by CDC.

Case classification
Probable: a case that is anti-HCV positive (repeat reactive) by EIA and has alanine aminotranferase (ALT or SGPT) values above the upper limit of normal, but the anti-HCV EIA result has not been verified by an additional more specific assay or the signal to cutoff ratio is unknown.

Confirmed: a case that is laboratory confirmed and that does not meet the case definition for acute hepatitis C.

Public Health Impact:

The revision will permit appropriate classification of true laboratory positive chronic or resolved HCV infections in the surveillance database.

Coordination:

Agencies for Response:

(1) James Hughes, MD
Director, National Center for Infectious Diseases
Centers for Disease Control and Prevention
National Center for Infectious Diseases, MS C-12
1600 Clifton Road, NE
Atlanta, GA 30333
404-639-3401
JHughes@cdc.gov

(2) Stephen Thacker, MD
Director, Epidemiology Program Office
Centers for Disease Control and Prevention
1600 Clifton Road, NE
Mailstop C-8
Atlanta, GA 30333
404-639-3661
sbt1@cdc.gov

Agencies for Information:

(1) Lyn Finelli, DrPH
Chief, Hepatitis Surveillance
Centers for Disease Control and Prevention
Division of Viral Hepatitis, MS G-37
1600 Clifton Road, NE
Atlanta, GA 30333

404-371-5910 (Telephone Number) LYF8@cdc.gov (Email Address)

(2) John Ward, MD
Chief, Division of Viral Hepatitis
Centers for Disease Control and Prevention
Division of Viral Hepatitis, MS G-37
1600 Clifton Road, NE
Atlanta, GA 30333

404-371-5900
Telephone Number Email Address

Submitting Author:

(1) Geoffrey Beckett, PA-C. MPH
Assistant State Epidemiologist
Division of Disease Control
Maine Bureau of Health
Station 11
Augusta, ME 04333-0011

207-287-2770
Telephone Number

Geoff.A.Beckett@Maine.gov
Email Address

provide a separate attachment with complete contact information.