

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 ratios 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

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).

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: (List only one name per agency, preferably an individual in a senior management position; complete contact information must be provided for acceptance to review.)

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