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anti-HCV test results are negative (screening-test–negative or

these results among those at low risk for HCV infection (*23,24*). Another sample should be collected for repeat anti-HCV testing (≥1 month later) or for HCV RNA testing.

NATs that detect HCV RNA also can be used as supplemental tests for anti-HCV. NATs are used commonly in clinical practice for diagnosis of acute and chronic HCV infection and for evaluating and managing patients with chronic hepatitis C.

Supplemental NAT Results

If the NAT result is positive in persons with a positive screening test result, NAT has the advantage of detecting the presence of active HCV infection as well as verifying the presence of anti-HCV (Box). If the NAT result is negative in persons with a positive screening test result, the HCV antibody or infection status cannot be determined. Among persons with these results, additional testing with RIBA is necessary to verify the anti-HCV result and determine the need for counseling and medical evaluation (Box); if the anti-HCV screening test results are judged falsely positive (i.e., RIBA-negative), no further evaluation of the person is needed; whereas if the anti-HCV screening test results are verified as positive by RIBA, the person should undergo medical evaluation, including

ratios

Estimated Costs of Implementing Reflex Supplemental Testing Based on Screening-Test–Positive S/Co Ratios

To assist laboratories in assessing the potential financial impact of implementing reflex supplemental testing for screening-test–positive samples with low s/co ratios, the incremental costs associated with such testing were estimated for three hypothetical populations of 10,000 persons each, representing anti-HCV prevalences of 2%, 10%, and 25%, respectively (similar to those of the groups evaluated previously). For each population, the costs of performing the screening test (by using EIAs as the example) and each of two different supplemental testing schemes (schemes 1 and 2) were compared with the cost of performing only the screening test (base scheme).

All schemes included performing a screening EIA on each sample and repeating initially reactive specimens in duplicate. Scheme 1 also included RIBA testing on all screening-test–positive samples with average s/co ratios <3.8, and scheme 2 included NAT testing on all screening-test–positive samples with average s/co ratios <3.8, followed by RIBA on those that were NAT-negative.

The increased costs for schemes 1 and 2 were calculated per sample tested compared with the base scheme. For RIBA and NAT, minimum and maximum costs were estimated; minimum costs were defined as costs for reagents only, and maximum costs were defined as costs incurred for tests performed by a referral laboratory. The following assumptions were made:

- The percentage of initially reactive samples that were repeatedly reactive (screening-test–positive) was assumed to be 90% in the groups with anti-HCV prevalences of 2% and 10%, and 95% in the group with anti-HCV prevalence of 25%.
- The proportion of screening-test–positive samples with average s/co ratios <3.8 and the proportion of such samples that tested RIBA-positive for each population was derived (Table 2).
- The proportion of screening-test–positive samples with average s/co ratios <3.8 that were NAT-positive was derived (Table 2) for the populations with anti-HCV prevalences of 2% and 10%. For the population with a prevalence of 25%, this proportion was assumed to be

on the s/co ratios of screening-test–positive results that can be implemented without substantial increases in testing costs.

Implementation of these recommendations will provide more reliable results for physicians and their patients, so that further counseling and clinical evaluation are limited to those

ratios from the initial reactive result and the one duplicate reactive result.

For those screening-test–positive samples that undergo reflex supplemental testing (according to the testing option chosen), the screening test anti-HCV results should not be reported before the results from the additional testing are avail-

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1. Why should laboratories verify anti-HCV screening-test–positive results with a more specific supplemental assay before reporting the results? (*Indicate all that apply.*)