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## Discontinuation of Hepatitis C RIBA Testing at the Alaska State Virology Laboratory

### Background

Hepatitis C virus (HCV) is a bloodborne pathogen that has infected approximately 4 million persons in the United States. Persons with HCV infection may feel well for many years before developing symptoms. Chronic liver disease does not usually occur until 10 to 20 years after initial infection. **Routine HCV testing of the general population is NOT recommended; testing should be offered to persons with specific risk factors or recognized exposures.**<sup>1</sup>

### Available HCV Tests

HCV diagnostic tests include third generation enzyme immunoassays (EIA-3) and recombinant immunoblot assays (RIBA) to detect HCV antibody; and nucleic acid tests, such as polymerase chain reaction (PCR), to detect the presence of HCV RNA (ribonucleic acid), which indicates current infection with HCV. Until August 2004, the Alaska State Virology Laboratory (ASVL) in Fairbanks performed EIA-3, RIBA, and qualitative PCR tests to evaluate specimens for HCV infection. However, analysis of HCV test results has led to the decision to discontinue RIBA testing.

### Results of HCV Testing at ASVL

From January 1, 2003 – September 29, 2004, ASVL evaluated 9,770 serum specimens for HCV using EIA-3; 745 (8%) were repeatedly reactive. All 745 specimens underwent supplemental testing (Figure 1). Results were stratified by signal-to-cut off (s/co) ratio; 94% of the EIA-3 reactive samples were strongly reactive, s/co ratio of =3.8.<sup>2</sup>

Among strongly reactive specimens that were PCR negative, none were RIBA negative and 9% (4/44) were indeterminate. Thus, a strongly reactive EIA screening test result is predictive of a positive RIBA result, and precludes the need to perform RIBA testing to confirm antibody status. Conversely, among weakly reactive specimens that were PCR negative, 51% (20/39) were RIBA negative, and 38% (15/39) were indeterminate. Only 10% (4/39) were RIBA positive. Thus, a weakly reactive EIA test result is

predictive of a negative or indeterminate RIBA result. Antibody to HCV cannot be confirmed.

### Discussion

Interpreting HCV supplemental test results can be challenging. A positive HCV PCR test indicates that virus is currently present in the blood. Because HCV viremia can be transient, a single negative PCR test does not rule out active infection. A positive RIBA test indicates that HCV antibody is present in the blood; however, infection with HCV may be current or resolved. PCR testing is still needed to confirm active infection. This ambiguity makes RIBA tests less clinically useful than PCR tests.

In addition to clinical usefulness, the decision to use a supplemental test should take into account test cost and the likelihood of a definitive result. RIBA tests are expensive to perform. The overall likelihood of a definitive result is quite low. As well, test-kit instructions recommend re-testing indeterminate specimens in 6-12 months. If follow-up tests are also indeterminate, continued re-testing is recommended with no definitive interpretation of results.

ASVL serial HCV test results suggest that RIBA tests often do not contribute to characterizing a patient's HCV status. These data are consistent with other supplemental test result analyses from published reports.<sup>2</sup>

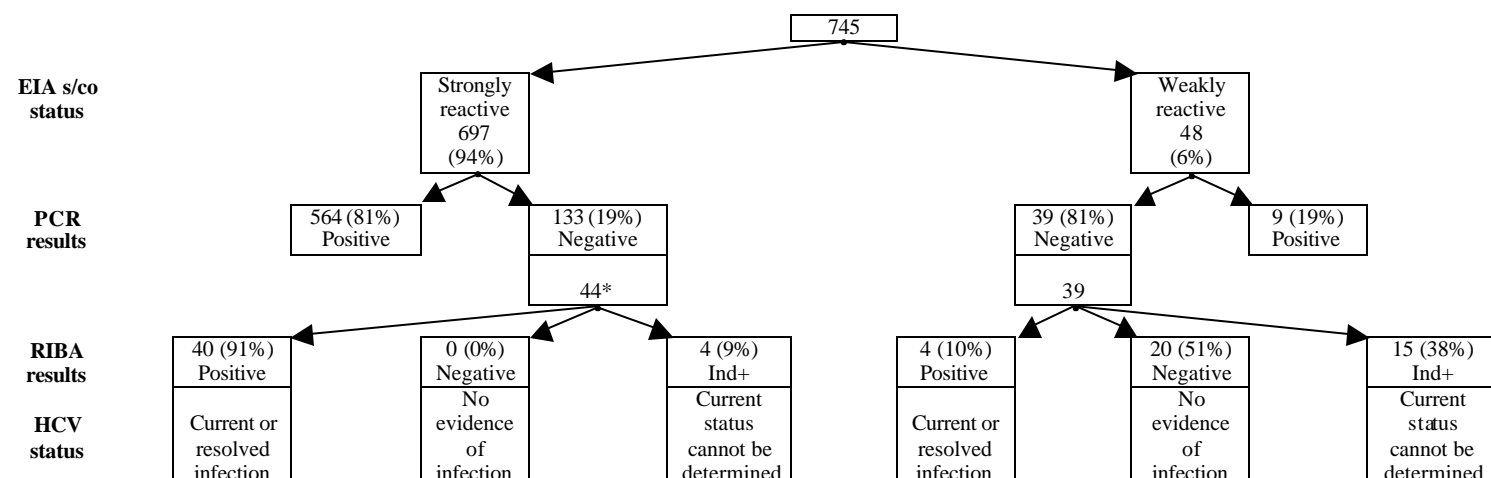
### Summary of HCV Testing Changes

The new HCV test algorithm at ASVL will include supplemental testing only by PCR for all EIA positive specimens. Supplemental HCV test result reports will indicate whether the EIA test was strongly or weakly reactive. **RIBA testing at ASVL will be discontinued.**

### References

- CDC. Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease. *MMWR*, Oct. 16, 1998, 47(RR-19).
- CDC. Guidelines for Laboratory Testing and Result Reporting of Antibody to Hepatitis C Virus. *MMWR*, Feb. 7, 2003, 52(RR-03).

Figure 1. Distribution of ASVL supplemental test results for EIA-3 reactive samples (n=745).



\*A sample set of 44 of the total 133 PCR negative specimens was tested using RIBA.

+Indeterminate.

For more information contact ASVL: (907) 474-7018.

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