

HEPATITIS C Ab RIBA NATIONWIDE REAGENT SUPPLY ISSUE

Dear Valued Client:

We recently received notice from our reference laboratory, Quest Diagnostics that they are **unable to perform the Hepatitis C Antibody RIBA testing due to a nationwide reagent supply issue.** Quest will be canceling any reflexes or orders for HCV RIBA received after February 16, 2011 and samples will be stored frozen until reagents become available. If the reagent is not available by March 15, 2011 the samples which are >30 days old would be discarded. In the meantime, **a suggested replacement confirmation assay would be the Hepatitis C Virus RNA Qualitative.**

Due to the uncertainty of the length of time that the HCV RIBA testing will be unavailable, Genesis Clinical Laboratory is implementing this new recommendation and will no longer reflex to the C-RIBA. The new recommendation will only affect the results that are Equivocal and Reactives that show a low signal to cut-off ratio. No changes will be made for Non-Reactives or Reactives with a high signal to cut-off ratio (>11.0).

This new recommendation is in compliance with the 2007 CDC guidelines for Viral Hepatitis C which states "that a person be considered to have serologic evidence of HCV infection only after an anti-HCV screening test reactive result has been verified by a more specific serologic test (e.g., RIBA) or a nucleic acid test (NAT)." This testing algorithm has also been expanded to include an option that uses the signal-to-cut off ratios of a screening test Reactive result to minimize the number of specimens that require supplemental testing and providing a result that has a high probability of reflecting the person's true antibody status ($\geq 95\%$ of the time). Genesis has been using this signal-to-cut off ratio to determine the necessity of the C-RIBA reflex on the reactive Hepatitis C antibodies.

The new recommendation for Equivocals and low Reactives (signal to cut-off ratio) is:

Presumptive Reactivity for Hepatitis C antibodies. Additional testing for HCV RNA PCR Qualitative and/or HCV RNA PCR Quantitative is recommended. Please contact Client Service 1-800-522-1425 opt 2 for test codes and sample requirements.

HCV-RNA/PCR QUAL.: TEST CODE 9300/HCRNAB

Specimen requirements: 2 ml of frozen EDTA plasma
Separate and freeze within 4 hours of collection, ship frozen on dry ice

HCV VIRAL LOAD (HCV RNA/PCR QT): TEST CODE 9349/HERNAB

Specimen requirements: 3 ml of frozen EDTA plasma
Separate and freeze within 6 hours of collection, ship frozen on dry ice

The HCV-RNA PCR Qual and Quant will provide more reliable results for physicians and their patients, so that further counseling and clinical evaluations are limited to those confirmed to have been infected with HCV. This is especially critical for persons being tested for HCV infection for the first time and those being tested to determine the need for medical referral. It also improves public health surveillance systems.

As always, we want to make certain that we provide the optimum in quality patient care. Please call the Genesis Client Service Department 1-800-522-1425 opt 2 if you have any questions or would like to discuss this matter further.

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