HCV Confirmatory Algorithm Change Effective 4/20/20

Overview:

FDA Guidance titled “Further Testing of Donations that are Reactive on a Licensed Donor Screening Test for Antibodies to Hepatitis C Virus; Guidance for Industry” was released on October 2, 2019 and recommends that CTS modify our current HCV reflex testing algorithm to support these best practices. This communication provides details for the addition of Grifols Procleix discriminatory HCV NAT (dHCV) to the current Prism HCV reactive algorithm for all NAT nonreactive (or not tested) donation samples. Please click the links to view the new algorithm and flowchart documents. Updated versions of the CTS Interpretation Information Sheets for Hepatitis will be provided as soon as they are available and will be posted on the CTS website on the day of implementation.

Addition of dHCV to the CTS HCV Serology reflex algorithm:

All Prism HCV repeatedly reactive donation samples that are Procleix Ultrio Plus NAT nonreactive or not tested, will be further tested using the Procleix dHCV test. This reflex algorithm change will also impact samples submitted directly to the Phoenix Special Testing Lab for routine HCV screening including reflex testing using the CTS-00173 Request Form.

- If the Procleix dHCV test is reactive, no further testing is required to confirm HCV infection because the Procleix assay is approved for use as a supplemental test to confirm HCV infection.
- If the Procleix dHCV test is nonreactive or not tested, the donation sample will be routed for additional supplemental testing using an alternate manufacturer donor screening assay.

The Procleix dHCV result interpretation will be reported from the CTS SD_Net computer system.

- For clients receiving electronic confirmatory result files from the SD_Net computer system, the test code will be “PUPHCVNAT”.

NOTE: Clients receiving electronic routine discriminatory dHBV, dHCV, dHIV results from LifeTrak need to evaluate the ability to receive confirmatory results electronically using a different test code for dHCV results from SD_Net.
• Results will be reported as Nonreactive, Reactive, Invalid, or Not Tested (QNS, Hemolyzed, Unacceptable Sample Age, etc.).

Impact to Clients:

Your facility computer systems, procedures, forms and letters that specifically reference the tests performed for HCV repeatedly reactive and/or discriminatory NAT results need to be evaluated to determine if changes are required for implementation on Monday, April 20, 2020.

Client Action Items

Evaluate current procedures, forms and letters to determine those directly referencing anti-HCV repeatedly reactive reflex testing as well as discriminatory HCV NAT.

• Evaluate potential changes to your computer systems related to the addition of dHCV testing for NAT negative (or not tested), anti-HCV repeatedly reactive samples.
  • Notify your customer service manager as soon as possible (no later than Monday, January 27, 2020) if you require CTS assistance for computer system validation or test and result code mapping.
  • Identify the resources required at your facility to implement the applicable changes.

Questions and Additional Information:

Please email your questions or requests for additional information to Lindsey Houghton (lhoughton@mycts.org) or O’Dina Hurlburt (ohurlburt@mycts.org).