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CPAL's Testing Algorithm for HCV Testing

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Introduction:

The Centers for Medicare & Medicaid Services (CMS) has determined that the evidence is adequate to conclude that screening for Hepatitis C Virus (HCV) is reasonable and necessary for the prevention or early detection of HCV infection. In response to this, the CDC recommended HCV testing be initiated with an FDA – approved test for antibody HCV followed by an HCV nucleic acid test (NAT) for persons who test positive. As a result, CPAL has initiated reflex HCV Viral Load testing on all HCV Antibody specimens (plasma or serum) that produce a result other than Non-Reactive.

Testing algorithm:

HCV IgG Screen Result	Supplemental testing
Non-reactive	No further testing suggested
Indeterminate	Reflex to HCV Viral Load
Reactive	Reflex to HCV Viral Load

Note: Reactive and Indeterminate specimens will be held for 14 days from date of collection to allow for an HCV genotype to be added upon request. Contact your ordering facility to request this testing.

Updated HCV IgG Screen and HCV Viral Load Comments:

A. HCV IgG Screen result is Indeterminate or Reactive (HCV screen S/CO is <5):

THIS IS AN UNCONFIRMED HCV SCREEN. CONFIRMATORY TEST RESULTS TO FOLLOW.

Current Guidelines* recommend that positive or indeterminate HCV screen results be confirmed with supplemental testing. For confirmation, an approved HCV Quantitative nucleic acid assay will be performed on this specimen. Results to follow.

*Testing for HCV Infection: An update of guidance for clinicians and laboratorians. MMWR 2013;62(18). (11/2016)

B. HCV IgG Screen result is Reactive (HCV screen S/CO is >= 5):

Current guidelines* recommend that HCV screen results be confirmed with supplemental testing such as nucleic acid testing unless the sample to cutoff ratio obtained from the HCV screen result is high (>=5 for the Abbott Architect HCV Assay). The sample to cutoff ratio result for this specimen is high (>=5) and is considered a positive result. This result probably indicates past or present infection. Samples with high S/CO ratios usually (about 95% of the time) confirm positive, but <5 of every 100 might represent false positives. HCV Viral load testing will be performed.

Results to follow.

*Testing for HCV Infection: An update of guidance for clinicians and laboratorians. MMWR 2013;62(18). (11/2016) Pennsylvania law requires the lab to report this result to the Pennsylvania Department of Health.

C. HCV Viral Load Interpretive Data:

HCV PCR Quant (IU/mL) Reference range: Not Detected

HCV Viral Load Result (IU/mL)	Interpretation
Not Detected	HCV RNA not detected. No current HCV infection. Repeat HCV RNA testing if the person tested is suspected to have had HCV exposure within the past 6 months or has clinical evidence of HCV disease.
<15 IU/mL	Low level HCV Viremia, may indicate previous spontaneous or treatment related resolution of HCV infection. Repeat HCV RNA testing if the person tested is suspected to have

	had HCV exposure within the past 6 months or has clinical evidence of HCV disease.
15 to 24 IU/mL	Low level HCV Viremia, may indicate previous spontaneous or treatment related resolution of HCV infection. Repeat HCV RNA testing if the person tested is suspected to have had HCV exposure within the past 6 months or has clinical evidence of HCV disease.
>= 25 IU/mL	Indicative of a current HCV Infection

Specimens with HCV VL results >= 15 IU/mL will be held for 14 days from date of collection to allow for an HCV genotype to be added upon request.

Significant differences exist in the quantitative values generated by different laboratory HCV viral load assays. It is recommended that serial patient testing be performed using a consistent method. Quantitation of HCV RNA is dependent on the number of virus particles present in the specimen and may be affected by specimen collection methods, patient factors (e.g. age, presence of symptoms), and stage of infection. Though rare, mutations in the highly conserved regions of the viral genome covered by the primers and/or probe used in this assay method may result in the under-quantitation of or failure to detect the presence of the virus in this circumstance. All results must be interpreted within the context of all relevant and clinical laboratory findings.

Viral load values greater than 100 million will be reported using scientific exponential notation.

****WARNING****
The HCV RNA assay is NEVER to be used as a screening test for the presence of HCV in blood or blood products.

References:

1. Roche COBAS AmpliPrep/COBAS TaqMan HCV Test, v2.0 package insert, May, 2016.