Review of HCV Labs and Screening Guidelines

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AASLD Screening Recommendations

One-Time Hepatitis C Testing

Recommendations for One-Time Hepatitis C Testing		
RECOMMENDED	RATING 3	
One-time, routine, opt out HCV testing is recommended for all individuals aged 18 years or older.	I, B	
One-time HCV testing should be performed for all persons less than 18 years old with activities, exposures, or conditions or circumstances associated with an increased risk of HCV infection (see below).	I, B	
Prenatal HCV testing as part of routine prenatal care is recommended with each pregnancy.	I, B	
Periodic repeat HCV testing should be offered to all persons with activities, exposures, or conditions or circumstances associated with an increased risk of HCV exposure (see below).	IIa, C	
Annual HCV testing is recommended for all persons who inject drugs, for HIV-infected men who have unprotected sex with men, and men who have sex with men taking preexposure prophylaxis (PrEP).	IIa, C	

Risk activities

Injection drug use (current or former, including those who injected only once)

Intranasal illicit drug use

Use of glass crack pipes

Male engagement in sex with men

Engagement in chem sex (defined as the intentional combining of sex with the use of particular nonprescription drugs in order to facilitate or enhance the sexual encounter [Bourne, 2015])

Risk exposure

- Persons on long-term hemodialysis (ever)
- Persons with percutaneous/parenteral exposures in an unregulated setting
- Healthcare, emergency medical, and public safety workers after needlestick, sharps, or mucosal exposure to HCVinfected blood
- Children born to HCV-infected women
- Recipients of a prior transfusion or organ transplant, including persons who:
 - Were notified that they received blood from a donor who later tested positive for HCV
 - Received a transfusion of blood or blood components, or underwent an organ transplant before July 1992
 - Received clotting factor concentrates produced before 1987
- Persons who were ever incarcerated

Other conditions and circumstances

HIV or HBV infection

Sexually active persons about to start preexposure prophylaxis (PrEP) for HIV

Chronic liver disease and/or chronic hepatitis, including unexplained elevated alanine aminotransferase (ALT) levels

Solid organ donors (living and deceased) and solid organ transplant recipients

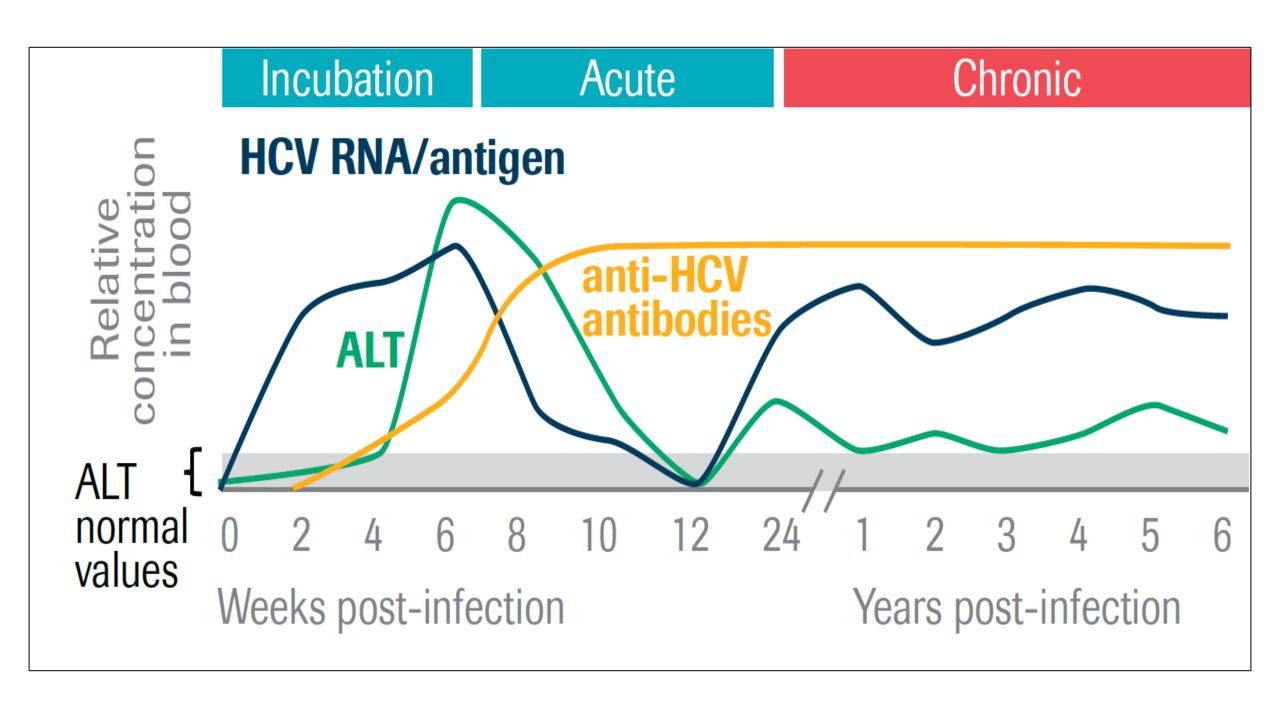
Routine HCV tests

Hepatitis C antibody (HCV Ab)

Quantitative Hepatitis C RNA (HCV PCR)

Hepatitis C genotype (HCV GT)





Screening for hepatitis C

- Hepatitis C Antibody testing (HCV Ab)
 - Sensitivity and specificity approaching 100%
 - First positive around 8 weeks after exposure
 - Positive for life
 - Option to order with <u>reflex</u>
 PCR



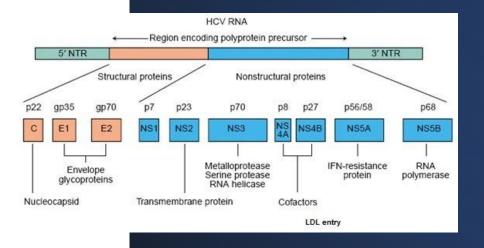
Point of care testing

- FDA approved test OraQuick rapid HCV antibody test
- Rapid results -20 minutes
- Equivalent efficacy and specificity
 - Tester dependent
- No rapid confirmatory testing available in the US at this time



Confirmatory testing

- Hepatitis C PCR (HCV PCR)
- Results
 - Quantifiable 15 -100,000,000
 IU/mL
 - may be detectable below 15



HCV genotypes

- 6 main genotypes (1-6)
 - Subtypes (ex. GT1a, GT1b)
- GT 1 is the most prevalent genotype in the USA
- Higher prevalence of GT 3 in intravenous drug users
- Relevance
 - Treatment outcomes
 - Re-infection vs treatment failure



Recommendations for Initial HCV Testing and Follow-Up

DECOMMENDED	DATING
RECOMMENDED	RATING 1
HCV-antibody testing with reflex HCV RNA polymerase chain reaction (PCR) testing is recommended for initial HCV testing.	I, A
Among persons with a negative HCV-antibody test who were exposed to HCV within the prior 6 months, HCV-RNA or follow-up HCV-antibody testing 6 months or longer after exposure is recommended. HCV-RNA testing can also be considered for immunocompromised persons.	I, C
Among persons at risk of reinfection after previous spontaneous or treatment-related viral clearance, HCV-RNA testing is recommended because a positive HCV-antibody test is expected.	I, C
Quantitative HCV-RNA testing is recommended prior to initiation of antiviral therapy to document the baseline level of viremia (ie, baseline viral load).	I, A
HCV genotype testing may be considered for those in whom it may alter treatment recommendations.	I, A
Persons found to have a positive HCV-antibody test and negative results for HCV RNA by PCR should be informed that they do not have evidence of current (active) HCV infection but are not protected from reinfection.	I, A

Confirming chronic infection

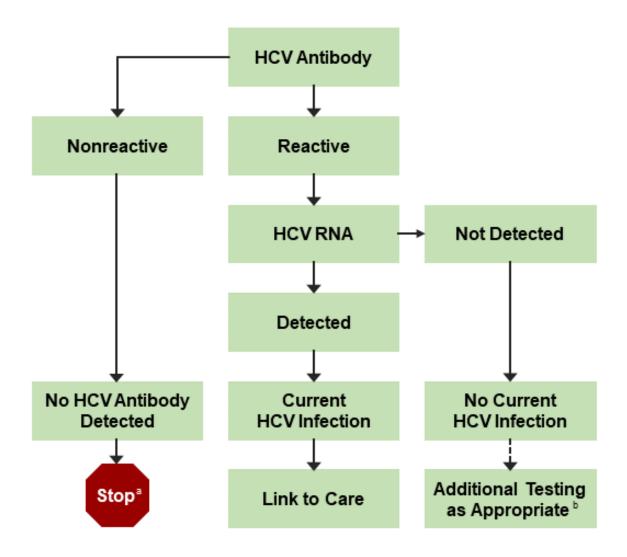




Two positive HCV PCR's 6 months apart or more

rational

Figure 1. CDC-Recommended Testing Sequence for Identifying Current HCV Infection



Additional labs following confirmation of active infection

Hepatic panel

BMP

CBC with plt

HIV

Hepatitis B surface antibody

Hepatitis B surface antigen

Hepatitis B core antibody total

HAV IgG (if vaccine status unknown)

Labs needed for treatment

AASLD recommends

- In the past 6 months
 - Hepatic function panel, CBC, INR, eGFR
- Anytime prior to starting
 - HCV RNA
 - HBV labs
 - HIV labs
- Before initiating therapy
 - Pregnancy testing

Medicaid

- In the past 3 months
 - HCV PCR
 - HBV labs
 - HIV screening
 - Pregnancy test
- Anytime prior to starting
 - HCV genotype

Labs for fibrosis staging

FIB 4

- Age
- AST
- ALT
- Platelet count

APRI

- AST
- ALT
- Platelet count



Lab requirements while on treatment

On treatment labs: AASLD simplified guidelines

- Non cirrhotic
 - None
- Compensated cirrhosis without prior treatment
 - Provider discretion

Post treatment assessment for cure: AASLD simplified guidelines

- After completion of 12 weeks of treatment
 - Liver panel
 - HCV PCR

Follow up after achieving SVR: AASLD simplified guidelines

Non cirrhotic

- Ongoing risk factors
 - Yearly HCV PCR and repeat whenever liver tests are elevated
- No ongoing risk factors
 - No follow up needed

Cirrhosis

- Needs ongoing monitoring for liver health and HCC screening
- Screen for reinfection if needed

SVR not achieved: AASLD simplified guidelines

- Non cirrhotic
 - Labs every 6-12 months
 - Hepatic panel
 - CBC with plt
 - INR



Questions?