Hepatitis C Virus (HCV) Point of Care RNA testing

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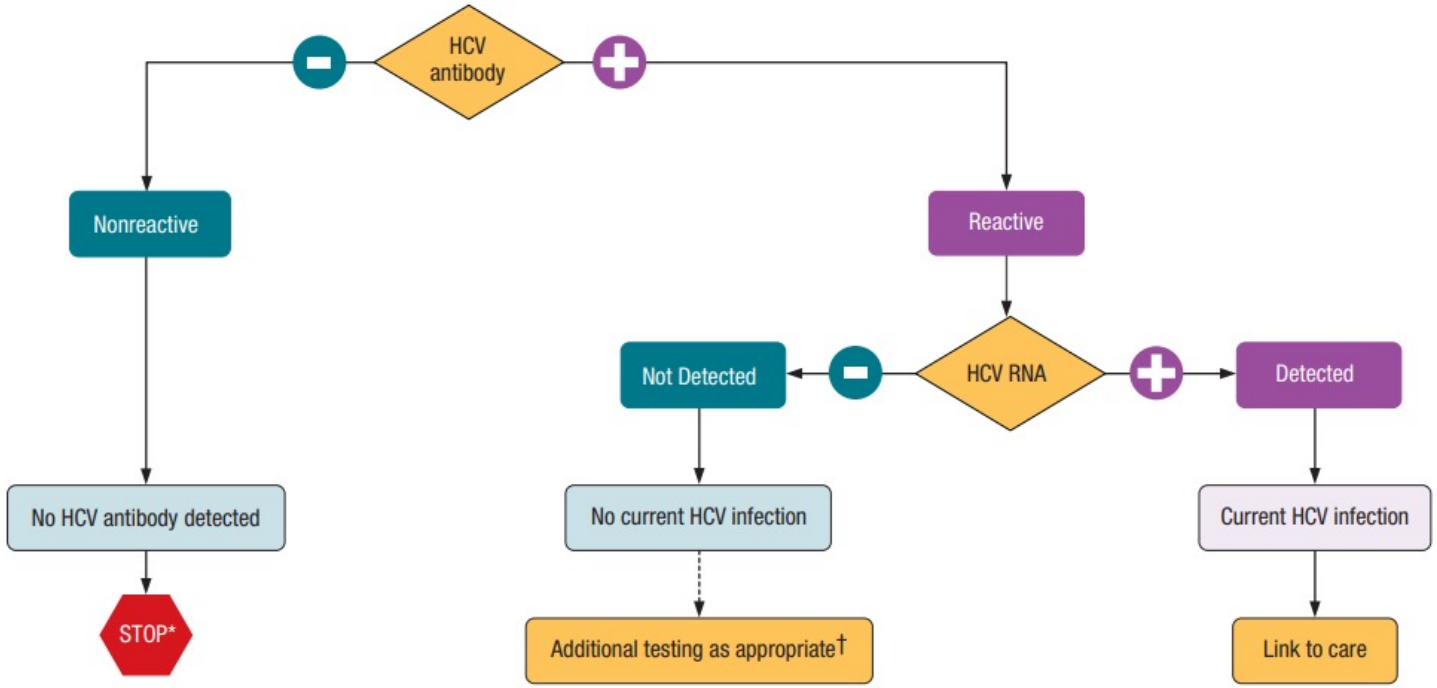
Disclosures

- Presenter is an employee of the United States government but any views expressed in this presentation are the presenter's own and do not reflect official US government policy.

- Any brand names that are used are for the purpose of education only and are not an endorsement of any specific medications or products.



* For persons who might have been exposed to HCV within the past 6 months, testing for HCV RNA or follow-up testing for HCV antibody is recommended. For persons who are immunocompromised, testing for HCV RNA can be considered.

† To differentiate past, resolved HCV infection from biologic false positivity for HCV antibody, testing with another HCV antibody assay can be considered. 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, or if there is concern regarding the handling or storage of the test specimen.

Source: CDC. Testing for HCV infection: An update of guidance for clinicians and laboratorians. MMWR 2013;62(18).

Challenges with traditional testing

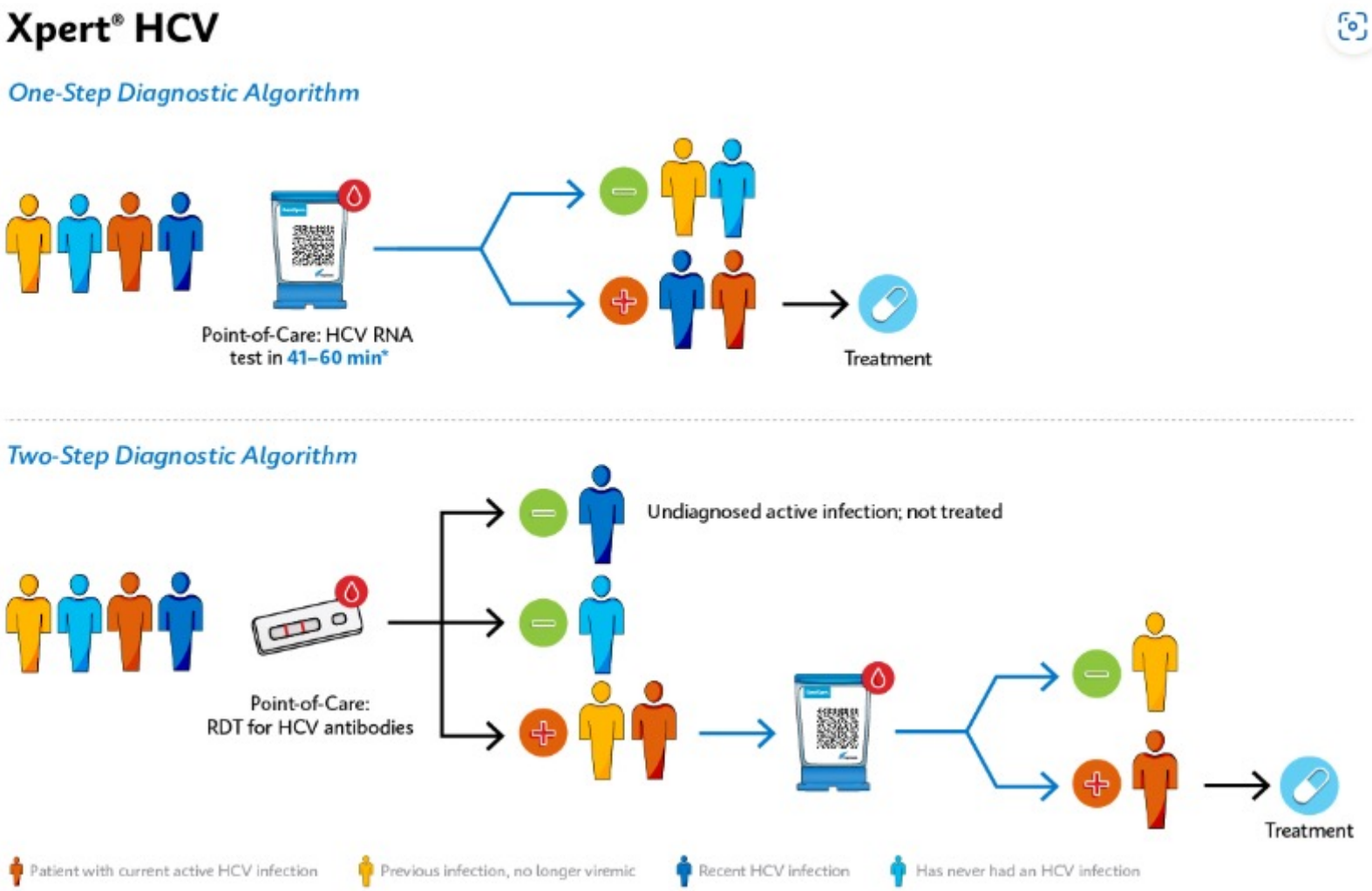
- **False negatives:** During acute HCV infection, antibody becomes detectable at ~ 8–11 weeks. Immunocompromised individuals may also not have detectable antibodies. HCV RNA becomes detectable 1-2 weeks after infection.

- New guidance from CDC in July 2023 recommended complete, automatic HCV RNA testing on all HCV antibody reactive samples to minimize patient visits and increase the number of patients diagnosed and treated.

- But this can still be logistically challenging due the amount of blood needed and lack of in-house HCV RNA testing at many facilities

Source: www.cdc.gov/hepatitis-c/hcp/diagnosis-testing

Point of Care HCV RNA Testing



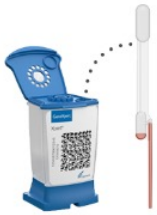
Point of Care HCV RNA Testing

1

Collect 250–500uL fingerstick whole blood in BD Micotainer*

2

Transfer 100uL of the sample into the cartridge using the pipette provided



3

Insert cartridge and start test

INFOGRAPHIC REFERENCES

* K2 EDTA Microcontainer (BD part number: 365974) not provided in the kit
Refer to the Xpert HCV pack insert 303-3318 Rev A for more information
US-IVD. *In Vitro* Diagnostic Medical Device.

- Test is CLIA-waived so can be performed at field sites such as mobile units or substance use treatment centers
- Minimum batch size = 1
- Limit of detection is 35 IU/mL genotype 1a, 136 IU/mL genotype 5 (WHO 6th International Standard)

Is HCV RNA testing only acceptable for diagnosis?

"HCV RNA testing is recommended for the diagnosis of current HCV infection among people who might have been exposed to HCV within the past 6 months, regardless of HCV antibody result."

"Suspected exposure may be inferred from the patient's history or the context and setting of the patient encounter (e.g., inferred potential exposure among people who inject drugs presenting to a syringe service program)."

Source: www.cdc.gov/hepatitis-c/hcp/diagnosis-testing

Point of Care HCV RNA Considerations

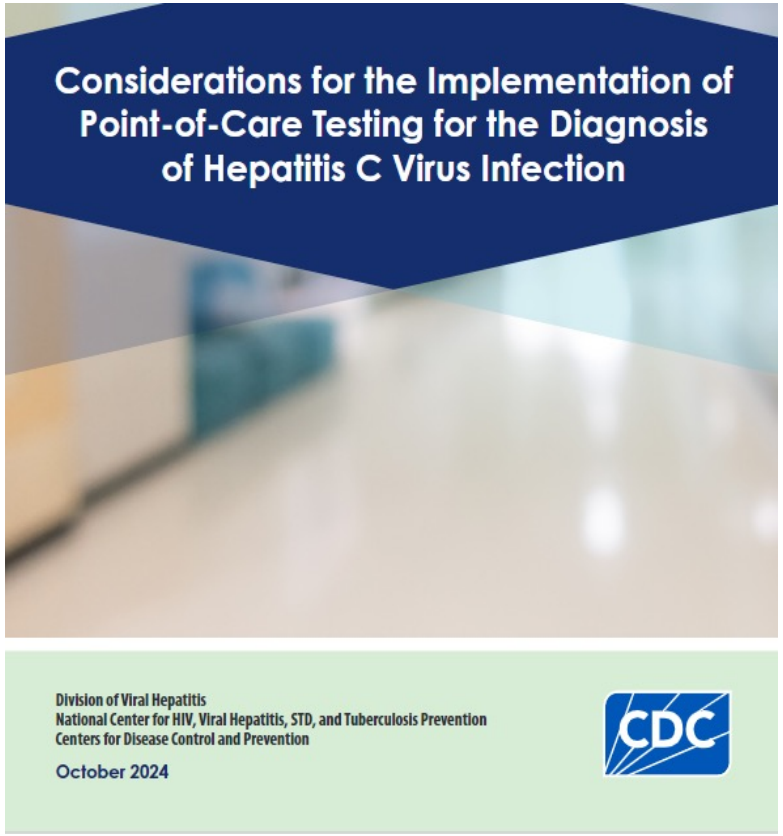


Table 4. Setting Characteristics Influencing HCV Testing Approach

High Hepatitis C Prevalence	Low to Moderate Hepatitis C Prevalence
Favors a single-step HCV RNA testing strategy.	Favors a two-step anti-HCV to HCV RNA testing strategy.
Brief Encounter	**Longitudinal Follow Up**
Favors POC testing with immediate treatment initiation or linkage to care.	Either POC or laboratory-based testing may be appropriate.
Phlebotomy and Laboratory Access	**No Phlebotomy and Laboratory Access**
Favors laboratory testing, especially in settings with established screening for multiple pathogens.	Favors POC testing.
High Client Volume	**Low Client Volume**
May favor a two-step anti-HCV to HCV RNA testing due to testing capacity limits of the POC HCV RNA instrument.	Implementing POC HCV RNA testing may be unfeasible due to cost or operational considerations.

Ideas for POC HCV RNA Testing in Gallup

- Expanding our current HCV Emergency Department (ED) screening program to include same day HCV treatment start (likely would use a 2 step testing model due to the large amount of patients screened in our ED)
- Partnering with local Detox and Recovery Centers with POC RNA testing on site with rapid linkage to care (one step model)
- Use of POC RNA testing on a mobile unit for "Street Outreach" with same day treatment start (one step model)

Questions/Comments

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References

- **Considerations for the Implementation of Point-of-Care Testing for the Diagnosis of Hepatitis C Virus Infection** October 2024 Centers for Disease Control and Prevention (U.S.). National Center for HIV/AIDS, Viral Hepatitis, STD, and TB PreventionDivision of Viral Hepatitis
- www.cdc.gov/hepatitis-c/hcp/diagnosis-testing