

Viral Hepatitis Prevention and Surveillance Virtual
Learning Collaborative

Solutions to Increase Reflex HCV RNA Testing: Quest Diagnostics

Presented by:

Holly Batterman MD

Medical Director, Infectious Diseases

Quest Diagnostics, Nichols Institute

San Juan Capistrano, California

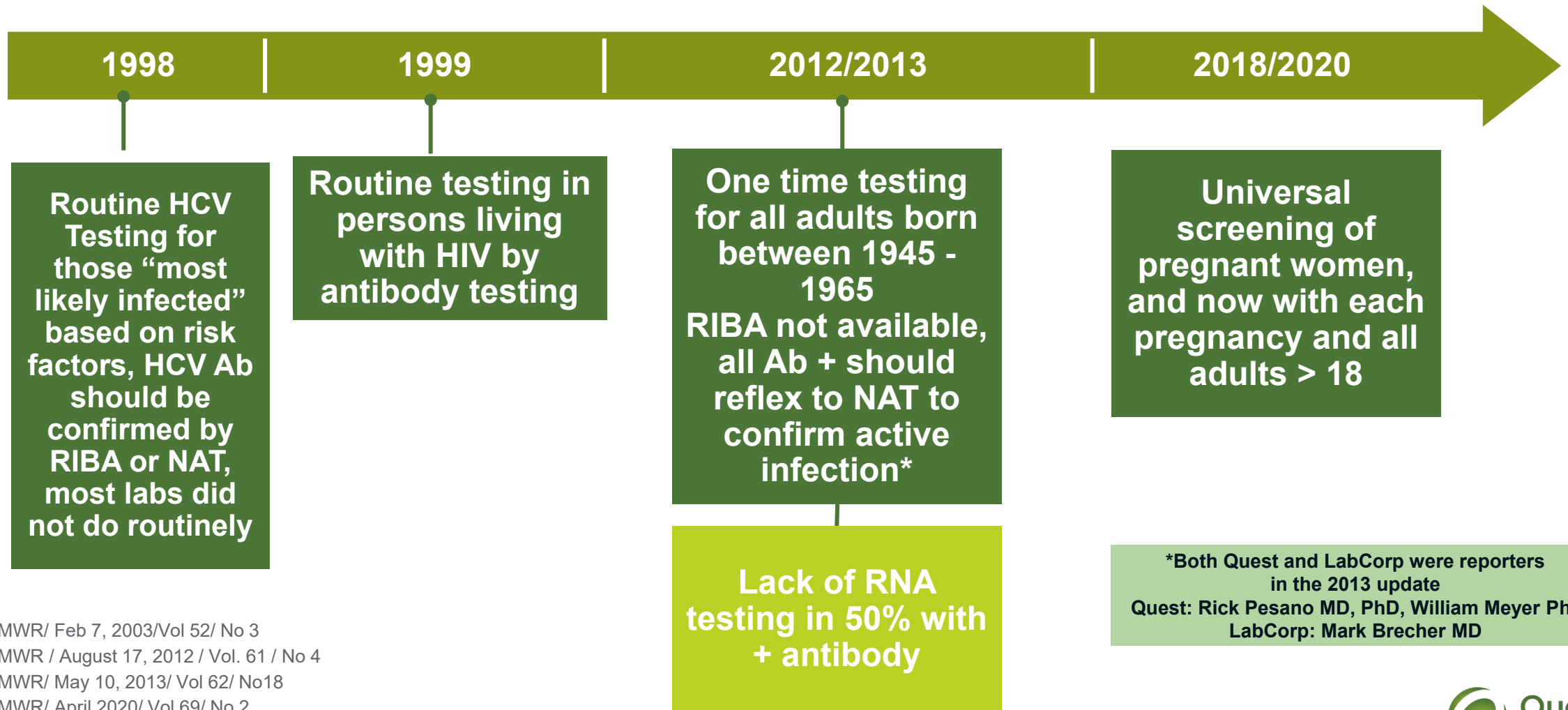
May 25, 2022



Timeline of HCV Screening and Testing Recommendations

1988: HCV identified as cause of Non A- Non B Hepatitis

1992: universal blood testing initiated



MMWR/ Feb 7, 2003/Vol 52/ No 3
MMWR / August 17, 2012 / Vol. 61 / No 4
MMWR/ May 10, 2013/ Vol 62/ No18
MMWR/ April 2020/ Vol 69/ No 2

Steps to Discontinue the Stand-Alone HCV AB Test Code at Quest

- We made the decision to discontinue the stand-alone antibody code based on the scientific data and the guidelines which supports more accurate diagnosis and outcomes.
- The medical and scientific teams reviewed the literature and guidelines, wrote a white paper to present to corporate compliance and quality for approval in 6/2015
- Team formed with project manager and commercial, medical/scientific directors, database, identified all codes affected to be able to notify clients appropriately and perform the necessary database work
- Formal client notification 30 days required for test code changes
 - In addition, approved Client letter distributed to provide additional information of rationale
- Discontinuation November 9, 2015:

Client Resources Available

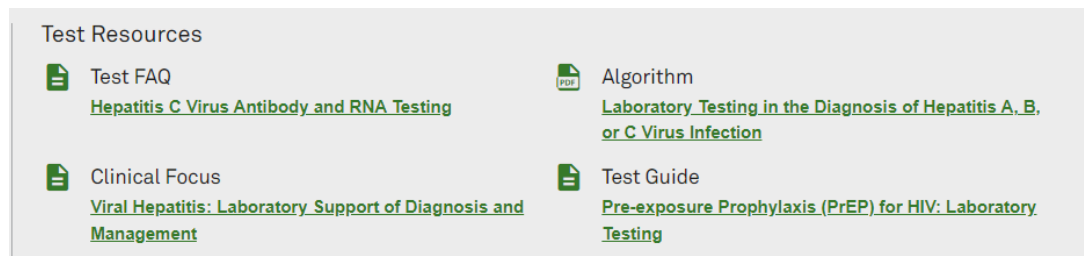
Test Code 8472: Hepatitis C Antibody with Reflex to HCV, RNA, Quantitative, Real-Time PCR, CPT 86803

Quest Test Center

- <https://testdirectory.questdiagnostics.com>
- Can search for any test, and all Hepatitis-related tests available
- On each tests there are linked resources

Some helpful links and resources

- “Fight hepatitis with comprehensive A-E testing” brochure



The screenshot shows a 'Test Resources' menu with four items, each with a document icon and a PDF icon:

- Test FAQ
[Hepatitis C Virus Antibody and RNA Testing](#)
- Clinical Focus
[Viral Hepatitis: Laboratory Support of Diagnosis and Management](#)
- Algorithm
[Laboratory Testing in the Diagnosis of Hepatitis A, B, or C Virus Infection](#)
- Test Guide
[Pre-exposure Prophylaxis \(PrEP\) for HIV: Laboratory Testing](#)

If you want to be a Quest Diagnostics client

- Contact Tony Falvo, National Director, Public Health/Government Strategies and Solutions

Other Hepatitis Resources

- Available on the Quest Website

- Viral hepatitis: Laboratory Support of Diagnosis and Management | Clinical Focus | Quest Diagnostics

Last updated January 2021, it outlines Viral Hepatitis in general, and includes specific test codes that Quest Diagnostics offers for viral hepatitis:

- For HCV: some highlighted test codes:

Test Code 37811	Hepatitis C Viral RNA, Genotype, LiPA Determination of hepatitis C genotype is often required to select the most appropriate direct acting agent(s) (DAA) for the treatment of hepatitis C. Some DAA's are only effective for the treatment of hepatitis C genotype 1, whereas others may be used for additional genotypes. Refer to the package inserts of the relevant DAA's for guidance. A concurrent patient HCV viral load of ≥ 300 IU/mL is required for this test.
Test Code 94345	Hepatitis C Antibody with Reflex to HCV RNA, PCR w/Reflex to Genotype, LiPA Hepatitis C Virus (HCV) is the major cause of hepatitis. Making positive HCV Ab tests reflex to confirmatory molecular testing is necessary to confirm active HCV infection. Providing a second reflex to perform genotyping on HCV isolates when RNA is detected is also a necessary step before starting therapy. This double reflex will reduce the percentage of antibody-positive patients who lack appropriate confirmatory RNA testing and who do not have ...
Test Code 92447	Hepatitis C Viral RNA Genotype 1 NS5a Drug Resistance For detection of mutations in the NS5a gene associated with resistance to NS5a inhibitors (examples: daclatasvir, ledipasvir, ombitasvir, elbasvir and velpatasvir). Testing for NS5a resistance-associated variants prior to initiation of treatment with elbasvir plus grazoprevir in HCV genotype 1a infected patients is recommended.
Test Code 92204	Hepatitis C Viral RNA Genotype 1 NS5b Drug Resistance For detection of mutations in the Genotype 1 NS5b gene associated with resistance to nucleotide analog NS5b polymerase inhibitors (example: sofosbuvir, a nucleotide analog inhibitor of HCV NS5b polymerase).
Test Code 90924	Hepatitis C Viral RNA Genotype 1 NS3 Drug Resistance This assay may be used to detect grazoprevir, simeprevir and paritaprevir resistance-associated NS3 mutations in genotype 1 NS3 protease inhibitor treatment-experienced patients and also the Q80K polymorphism in patients being considered for a simeprevir-containing regimen.

Hepatitis B Testing Resources

- Hepatitis B Screen Panel with Reflexes: **launched 2021**
 - Includes:
 - Hepatitis B Surface Antigen with Reflex Confirmation
 - Hepatitis B Core Antibody, Total, with Reflex to IgM
 - Hepatitis B Surface Antibody, Quantitative
 - Interpretation of results
 - FAQ and Test Summary on website
- HBV viral load and resistance testing
- Additional tests such as Hepatitis Be Antigen, Hepatitis Be Antibody
- Hepatitis D testing: Antibody (IgM, and Total), HDV Qualitative and Quantitative viral load testing (Real-time PCR)

Other Potentially Useful Test Panels

- **PrEP HIV Baseline, Female Panel with Reflexes** [includes hCG, Cr, HIV 4th gen, HCV Ab with reflex PCR/Genotype, HBsAg, HBsAb, HBcore Total AB reflex IgM, RPR, CT/NG TMA]
- **PrEP HIV Baseline, Male Panel with Reflexes** [includes Cr, HIV 4th gen, HCV Ab with reflex PCR/Genotype, HBsAg, HBsAb, HBcore Total AB reflex IgM, RPR, CT/NG TMA]
- **PrEP HIV Monitoring, Female Panel** [includes hCG, Cr, HIV 4th gen, RPR, CT/NG TMA]
- **PrEP HIV Monitoring, Male Panel** [includes HIV 4th gen, RPR, CT/NG TMA]
- **Pre-biologic/biosimilar Screen Panel, HCV/HBV with Reflexes and QFT** [includes HBsAg, HBsAb, HBcore total AB reflex IgM, HCV AB reflex PCR/genotype]

Summary

- Quest Diagnostics discontinued the stand-alone HCV antibody code in 2015
- Only HCV antibody with reflex to HCV RNA quantitative PCR available for screening
- Other reflex panels maybe helpful, eg, Antibody to PCR to genotyping in one draw
- Quest Diagnostics offers full menu of complimentary HCV tests for management and monitoring of HCV and treatment
- Quest Diagnostics offer testing for other hepatitis viruses such as HAV, HBV, HDV as well as some additional panels
 - Pre Biologic panels, for use before starting patients on immunosuppressive therapies
 - HIV PrEP panels for ease of ordering when starting and monitoring patients on HIV prevention

Q & A