

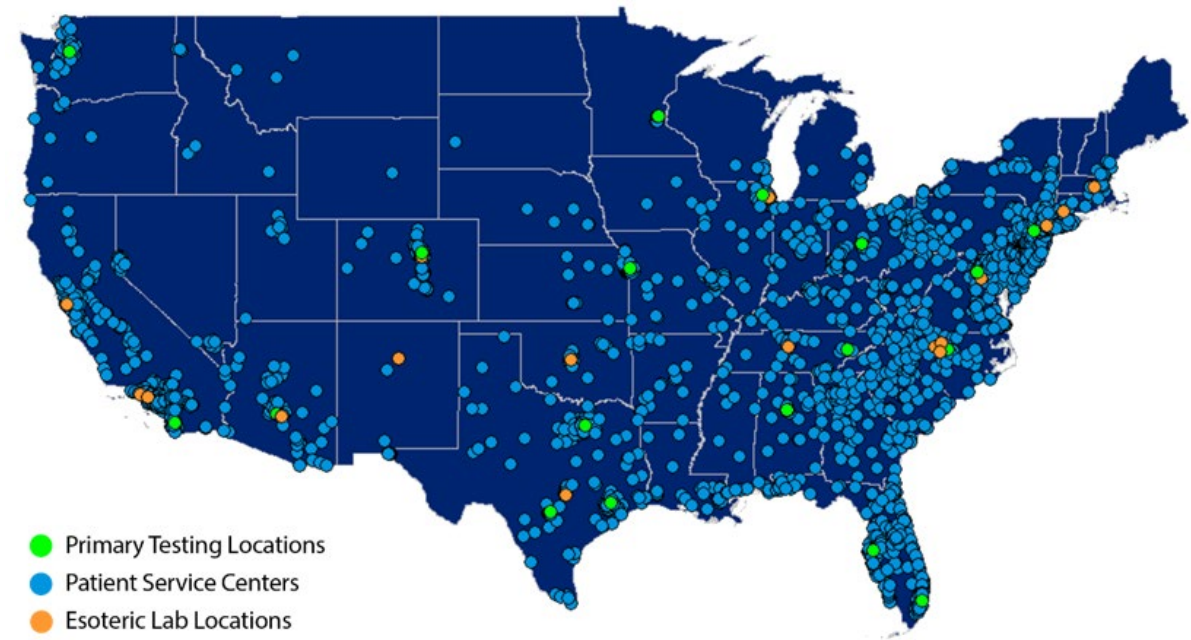
Guideline-Driven Hepatitis Testing, Labcorp

Laura Gillim, PhD
Technical Director, Science and Technology
Discipline Director, Infectious Disease Immunology



Labcorp at a Glance

- Integrated network of primary and specialty labs across US
- ~700 MDs and PhDs – Drug Development and R&D
- Standardization of testing platforms and methods
- Variety of customers
 - Physicians
 - Managed care organizations
 - Hospitals and health systems
 - Pharm
 - Patient consumers



Hepatitis Testing Initiative

- Align with current clinical guidelines/recommendations
- Standardize naming conventions to guide appropriate ordering
- Incorporate reflex testing based on published clinical algorithms to support timely, cost-effective, quality care
- Reduce the performance of unnecessary testing.
- Improve interpretive guidance

Hepatitis B Virus Screening and Diagnosis

| Test No. | Test Name | Use | Test Components | |
|---------------|---|--|------------------|--|
| 144473 | Hepatitis B Virus (HBV) Screening and Diagnosis | Screen for and diagnose hepatitis B virus (HBV) infection ¹⁻⁴ | Includes: | <ul style="list-style-type: none"> HBsAg Anti-HBc, Total Anti-HBs |
| | | | Reflex: | If Anti-HBc, Total is POSITIVE and Anti-HBs is negative, reflex to Anti-HBc, IgM. |

Interpretation:

| Interpretation | HBsAg | anti-HBs | anti-HBc | IgM anti-HBc |
|--|-------|----------|----------|--------------|
| Key – Analyte present: + Analyte absent: - Test not indicated: TNI | | | | |
| Susceptible/No evidence of infection | - | - | - | TNI |
| Immune due to natural resolved infection | - | + | + | - |
| Immune due to vaccination | - | + | - | TNI |
| Acute infection | + | - | + | + |
| Chronic infection | + | - | + | - |
| Interpretation unclear* | - | - | + | ± |

*Multiple possibilities: resolved infection (most common); false-positive anti-HBc (susceptible); “low-level” chronic infection”; resolving acute infection.

1. Terrault NA, Lok ASF, McMahon BJ, et al. Update on Prevention, Diagnosis, and Treatment of Chronic Hepatitis B: AASLD 2018 Hepatitis B Guidance. *Hepatology*. 2018 Apr;67(4):1560-1599.

2. Workowski KA, Bachmann LH, Chan PA, et al. Sexually Transmitted Infections Treatment Guidelines, 2021. *MMWR Recomm Rep*. 2021 Jul 23;70(4):1-187.

3. Abara WE, Oaseem A, Schillie S, McMahon BJ, Harris AM, High Value Care Task Force of the American College of Physicians and the Centers for Disease Control and Prevention. Hepatitis B Vaccination, Screening, and Linkage to Care: Best Practice Advice from the American College of Physicians and the Centers for Disease Control and Prevention. *Ann Intern Med*. 2017 Dec 5;167(11):794-804.

4. Schillie S, Vellozzi C, Reingold A, et al. Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices. *MMWR Recomm Rep*. 2018 Jan 12;67(1):1-31.

Hepatitis B Virus Patient Management

| Test No. | Test Name | Use | Test Components | |
|----------|--|---|-----------------|--|
| 144149 | Hepatitis B Virus (HBV) Patient Management | This panel is intended for use in the management of patients with chronic hepatitis B and to assess the efficacy of antiviral treatment. ^{1,3} | Includes: | • HBsAg |
| | | | Reflex: | If HBsAg is POSITIVE, reflex to HBeAg, Anti-HBe, HBV DNA, Quantitative, and ALT. |

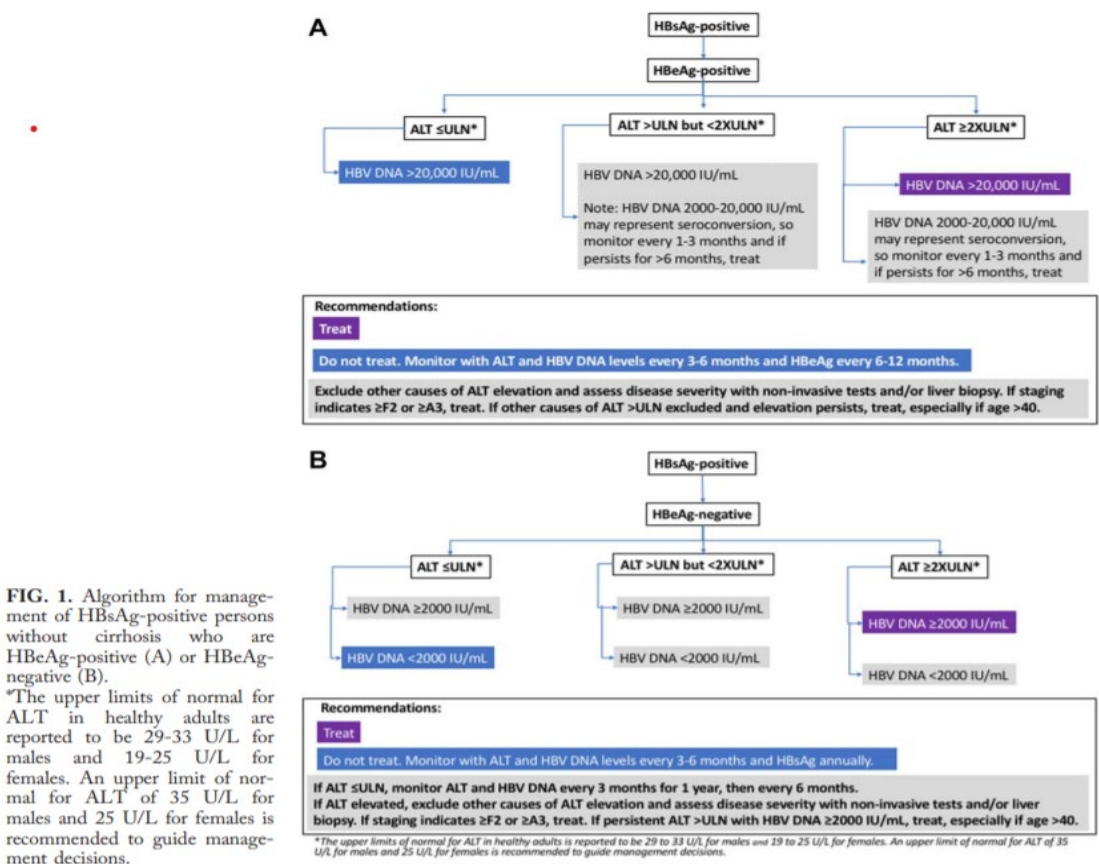


FIG. 1. Algorithm for management of HBsAg-positive persons without cirrhosis who are HBeAg-positive (A) or HBeAg-negative (B).
*The upper limits of normal for ALT in healthy adults are reported to be 29-33 U/L for males and 19-25 U/L for females. An upper limit of normal for ALT of 35 U/L for males and 25 U/L for females is recommended to guide management decisions.

ult NA, Lok ASF, McMahon BJ, et al. Update on Prevention, Diagnosis, and Treatment of Chronic Hepatitis B: AASLD 2018 Hepatitis B Guidance. *Hepatology*. 2018 4):1560-1599.
owski KA, Bachmann LH, Chan PA, et al. Sexually Transmitted Infections Treatment Guidelines, 2021. *MMWR Recomm Rep*. 2021 Jul 23;70(4):1-187.
WE, Oaseem A, Schillie S, McMahon BJ, Harris AM, High Value Care Task Force of the American College of Physicians and the Centers for Disease Control and ion. Hepatitis B Vaccination, Screening, and Linkage to Care: Best Practice Advice from the American College of Physicians and the Centers for Disease Control and ion. *Ann Intern Med*. 2017 Dec 5;167(11):794-804.

HBV Baseline Evaluation, HCV Direct-acting Antivirals

| Test No. | Test Name | Use | Test Components | |
|----------|---|---|-----------------|--|
| 144547 | HBV Baseline Evaluation, HCV Direct-acting Antivirals | Risk assessment and management of HBV infection status in patients prior to initiation of HCV treatment with direct-acting antiviral agents. ^{5,6} | Includes: | <ul style="list-style-type: none">HBsAgAnti-HBc, TotalAnti-HBs |
| | | | Reflex: | If HBsAg POSITIVE, reflex to HBV DNA, Quantitative. |



5. Whitsett M, Feldman DM, Pan CQ. Risk assessment and management of hepatitis B reactivation from direct-acting antivirals for hepatitis C. *Liver Research*. 2019 Jun;3(2):75-79.
6. US Food and Drug Administration. FDA Drug Safety Communication: FDA warns about the risk of hepatitis B reactivating in some patients treated with direct-acting antivirals for hepatitis C. FDA web site: <https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-warns-about-risk-hepatitis-b-reactivating-some-patients-treated>. Published Oct. 4, 2016. Accessed August 2021.

M. Whitsett et al., *Liver Research*, 3 (2019) 75-79

Viral Hepatitis Profiles (HAV, HBV, HCV)

| Test No. | Test Name | Use | Test Components | |
|----------|---|---|------------------|--|
| 144000 | Acute Viral Hepatitis (HAV, HBV, HCV) | Aid in the diagnosis of acute viral hepatitis due to infection with HAV, HBV, and/or HCV. | Includes: | <ul style="list-style-type: none"> • HAV IgM • anti-HBc, IgM • HBsAg • anti-HCV |
| | | | Reflex: | If anti-HCV total is POSITIVE will reflex to HCV RNA quantitative PCR. |
| 144552 | Viral Hepatitis Screening and Diagnosis (HAV and HBV) | Aid in the diagnosis of viral hepatitis due to infection with HAV and or HBV. | Includes: | <ul style="list-style-type: none"> • HBsAg • anti-HBs • anti-HBc total • anti-HAV total |
| | | | Reflex: | If anti-HBc total is POSITIVE will reflex to anti-HBc IgM. If anti-HAV total is POSITIVE will reflex to anti-HAV IgM. |
| 144025 | Viral Hepatitis Screening and Diagnosis (HBV and HCV) | Aid in the diagnosis of viral hepatitis due to infection with HBV and/or HCV. | Includes: | <ul style="list-style-type: none"> • HBsAg • anti-HBs • anti-HBc total • anti-HCV Total |
| | | | Reflex: | If anti-HBc total is POSITIVE will reflex to anti-HBc IgM. If anti-HCV total is POSITIVE will reflex to HCV RNA quantitative PCR. |
| 144445 | Viral Hepatitis Screening and Diagnosis (HAV, HBV, and HCV) | Aid in the diagnosis of viral hepatitis due to infection with HAV, HBV and/or HCV. | Includes: | <ul style="list-style-type: none"> • anti-HAV Total • HBsAg • anti-HBs • anti-HBc total • anti-HCV Total |
| | | | Reflex: | If anti-HAV Total is POSITIVE will reflex to HAV IgM. If anti-HBc, total is POSITIVE and anti-HBs is negative reflex to anti-HBc, IgM. If anti-HCV total is POSITIVE will reflex to HCV RNA quantitative PCR. |
| 144226 | Hepatitis A Virus (HAV) Antibody, Total with reflex to IgM | Aid in the diagnosis of active Hepatitis A (HAV) infection and differentiate between active and previous infection/vaccination. | Includes: | • anti-HAV Total |
| | | | Reflex: | If anti-HAV Total is POSITIVE will reflex to HAV IgM. |

Pregnancy, Initial Screening Profile

| Test Name | Components |
|--|--|
| Pregnancy, Initial Screening Profile 144053 | 005009 Complete Blood Count (CBC) with Differential |
| | 006015 Antibody Screen |
| | 006049 ABO Grouping and Rho(D) Typing |
| | 003772 Urinalysis, Complete with Microscopic Examination |
| | 008851 Urine Culture, Prenatal, with GBS |
| | 083935 HIV p24 Antigen/Antibody with Reflex to Confirmation |
| | 006510 HBV Surface Antigen (HBsAg) Screen, Qualitative |
| | 144050 HCV Antibody with Reflex to Quantitative Real-Time PCR |
| | 012005 RPR with Reflex to Titer and <i>Treponema pallidum</i> antibodies |
| | 183194 Chlamydia/Gonococcus, NAA |
| | 006197 Rubella Antibodies, IgG |

STI/ID Profiles

| Test Name | Components |
|---|--|
| Sexually Transmitted Infections (STI), with CT/NG NAA (144082) | <ul style="list-style-type: none"> • 012005 Syphilis • 144473 HBV screening and diagnosis • 144050 HCV w/ reflex to quant RNA • 183194 CT/NG NAA • 083935 HIV |
| Sexually Transmitted Infections (STI), with CT/NG/TV NAA (144027) | <ul style="list-style-type: none"> • 012005 Syphilis • 144473 HBV screening and diagnosis • 144050 HCV w/ reflex to quant RNA • 183160 CT/NG/Trich • 083935 HIV |
| Sexually Transmitted Infections (STI) (144011) | <ul style="list-style-type: none"> • 012005 Syphilis • 144473 HBV screening and diagnosis • 144050 HCV w/ reflex to quant RNA • 083935 HIV |

Challenges with Implementation of Guideline-Driven Reflex Testing

- ***Laboratory:***

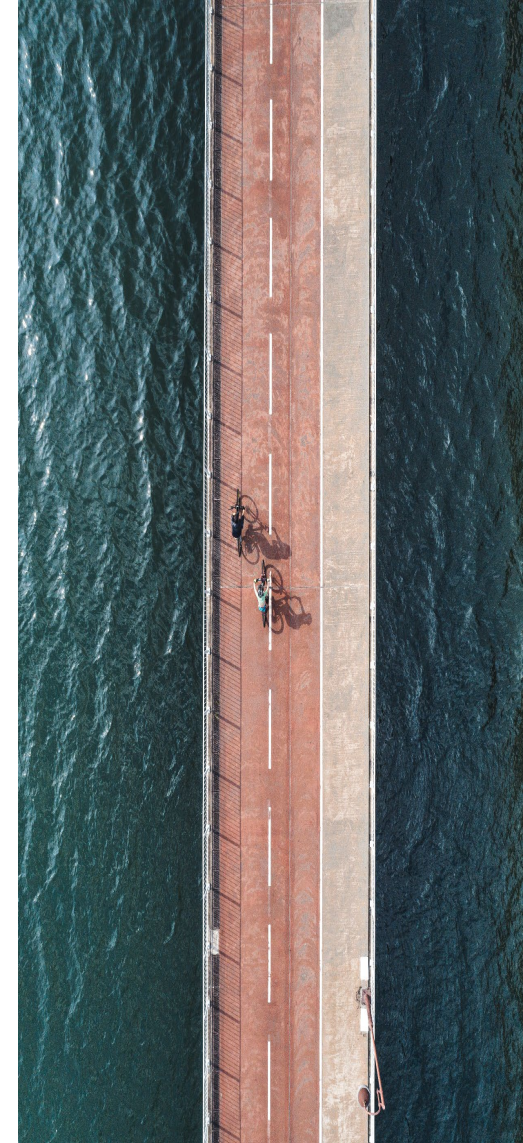
- LIS programming
- Reporting- reports look different lab LIS versus provider EMRs
- Identifying and changing all impacted profiles (published, unpublished, custom)
- Compliance and reimbursement
- Updating marketing material
- State Reporting

- ***Provider:***

- Lack of awareness of guidelines/recommendations
- Custom panels versus published Labcorp panel
- Client type (e.g., out of pocket versus insured)
- Concerns about additional costs
- Challenges with interpretation

Overview of the Timeline

- July 2021: launched the new hepatitis profiles
- March 2022: launched the Pregnancy, Initial Screening Profile and STI profiles
- May 2022: discontinued the “old” hepatitis profiles
- Ongoing/Underway:
 - Custom profiles including HCV must include the HCV Ab w/ reflex to RNA
 - Discussions around making HCV antibody alone unpublished and/or non-orderable.
 - Discontinuation of pregnancy profiles that lack HCV testing



Thank you.

