Guideline-Driven Hepatitis Testing, Labcorp

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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

<table>
<thead>
<tr>
<th>Test No.</th>
<th>Test Name</th>
<th>Use</th>
<th>Test Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>144473</td>
<td>Hepatitis B Virus (HBV) Screening and Diagnosis</td>
<td>Screen for and diagnose hepatitis B virus (HBV) infection&lt;sup&gt;1-4&lt;/sup&gt;</td>
<td>Includes: Anti-HBe, Total</td>
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<td>Anti-HBc, Total</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Reflex: If Anti-HBc, Total is POSITIVE and Anti-HBs is negative, reflex to Anti-HBc, IgM.</td>
</tr>
</tbody>
</table>
**Hepatitis B Virus Patient Management**

<table>
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</table>
| 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. | 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 HBsAg-positive (A) or HBsAg-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.

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*All references are cited in the document.*
# HBV Baseline Evaluation, HCV Direct-acting Antivirals

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<tbody>
<tr>
<td>144547</td>
<td>HBV Baseline Evaluation, HCV Direct-acting Antivirals</td>
<td>Risk assessment and management of HBV infection status in patients prior to initiation of HCV treatment with direct-acting antiviral agents.(^5,6)</td>
<td>Includes:</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>• HBsAg</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>• Anti-HBc, Total</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>• Anti-HBs</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Reflex:</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>If HBsAg POSITIVE, reflex to HBV DNA, Quantitative.</td>
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</tbody>
</table>


# Viral Hepatitis Profiles (HAV, HBV, HCV)

<table>
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<th>Test Components</th>
<th>Reflex</th>
</tr>
</thead>
</table>
| 144000  | Acute Viral Hepatitis (HAV, HBV, HCV) | Aid in the diagnosis of acute viral hepatitis due to infection with HAV, HBV, and/or HCV. | • HAV IgM  
• anti-HBC, IgM  
• HBsAg  
• anti-HCV | If anti-HCV total is POSITIVE will reflex to HCV RNA quantitative PCR. |
| 14452   | Viral Hepatitis Screening and Diagnosis (HAV and HBV) | Aid in the diagnosis of viral hepatitis due to infection with HAV and/or HBV. | • HBsAg  
• anti-HBs  
• anti-HBC total  
• anti-HAV total | 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. | • HBsAg  
• anti-HBs  
• anti-HBC total  
• anti-HCV Total | 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. | • anti-HAV Total  
• HBsAg  
• anti-HBs  
• anti-HBC total  
• anti-HCV Total | 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. | • anti-HAV Total | If anti-HAV Total is POSITIVE will reflex to HAV IgM. |
# Pregnancy, Initial Screening Profile

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

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Components</th>
</tr>
</thead>
</table>
| Sexually Transmitted Infections (STI), with CT/NG NAA (144082) | • 012005 Syphilis  
• 144473 HBV screening and diagnosis  
• 144050 HCV w/ reflux to quant RNA  
• 183194 CT/NG NAA  
• 083935 HIV |
| Sexually Transmitted Infections (STI), with CT/NG/TV NAA (144027) | • 012005 Syphilis  
• 144473 HBV screening and diagnosis  
• 144050 HCV w/ reflux to quant RNA  
• 183160 CT/NG/Trich  
• 083935 HIV |
| Sexually Transmitted Infections (STI) (144011) | • 012005 Syphilis  
• 144473 HBV screening and diagnosis  
• 144050 HCV w/ reflux 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.