



## Five Things Physicians and Patients Should Question

1

### Don't repeat HbA1c testing within 3 months of a previous result.

The lifespan of a HbA1c is approximately 90–120 days, and the full effects of a patient's change in behavior, diet, or newly adjusted medications will not be fully appreciated until all previous HbA1c in circulation are replaced (~90 days). Therefore, testing at time intervals earlier than 3 months may not allow enough time to pass to reach the expected target by the clinician. Testing at 6-month intervals may be considered when glycemic targets are consistently achieved.

2

### Don't perform an extensive work-up in otherwise healthy neutropenic patients of African or Middle Eastern ancestry prior to Duffy-null phenotype testing.

Individuals, typically of African or Middle Eastern ancestry, may present with an ANC <1500 cells/ $\mu$ L with no signs of recurrent infections, immunocompromise, or malignancy. Frequently, the lower ANC is a normal variant associated with the red blood cell Duffy-null phenotype [Fy(a-b-)] that should be confirmed by Blood Bank phenotyping. Asymptomatic Duffy-null individuals do not require additional testing and should not be denied clinical trial participation or prescription of certain medications (including chemotherapy) based on ANC alone.

3

### Don't order ANA and ENA unless the patient is suspected to have a connective tissue disease.

Testing for anti-nuclear antibody (ANA) and extractable nuclear antigen (ENA) should be avoided in the investigation of widespread pain or fatigue alone. Instead, testing should only be performed in patients suspected to have a diagnosis of a connective tissue disease (e.g., lupus, rheumatoid arthritis). ANA positivity can be as high as 20% in patients with non-rheumatic conditions and healthy individuals. For this reason, proper pre-test probability is important, and false positive results may lead to further unnecessary testing. Repeat testing is also not recommended unless the clinical picture changes significantly.

4

### Do not measure the INR in patients who are taking an anti-Xa inhibitor.

Anti-Xa inhibitors (e.g., rivaroxaban [Xarelto<sup>®</sup>], apixaban [Eliquis<sup>®</sup>]) are commonly prescribed anticoagulants. Their indications include (but are not limited to): reducing the risk of stroke or systemic embolism in patients with nonvalvular atrial fibrillation; treating deep venous thromboembolism (DVT) and pulmonary embolism; and DVT prophylaxis. Bleeding is a common complication from anti-Xa inhibitor use that may require reversal with andexanet alfa, prothrombin complex concentrate, or plasma. While the INR is commonly used to measure the anticoagulation effect of vitamin K antagonists (e.g., warfarin), it is insensitive for anti-Xa inhibitors, potentially leading to inappropriate patient management decisions.

5

### Don't employ a specific direct oral anticoagulant [DOAC] reversal agent without identifying the DOAC and estimating its plasma concentration.

In 2015, the US FDA approved idarucizumab as a reversal immunoglobulin specific for the direct thrombin inhibitor dabigatran. In 2018, andexanet alfa was approved as a factor Xa mimetic reversal agent for the direct anti-Xa oral anticoagulants rivaroxaban and apixaban.<sup>1</sup> Clinicians employ reversal agents to control major bleeding associated with presumed DOAC overdose when compression, blood product support, and antifibrinolytics are ineffective, often in preparation for an invasive procedure.<sup>2</sup> A reversal agent should be employed only when the clinician can identify the DOAC using, for instance, an anti-Xa assay\* or dilute thrombin time [DTT] assay\*, establish the likelihood that it is the bleeding source, and estimate its dose or plasma concentration.<sup>3</sup> In addition to their documented risk of ischemic complications, reversal agents are maintained in collaborative inventory systems with controlled access, owing to scarcity and costs.<sup>4</sup> Andexanet alfa, for instance, costs \$27,500 for a low dose regimen and \$49,500 for a high dose, and CMS reimbursement is limited to 50% of the low dose investment.<sup>5</sup> A rapid urinary "dipstick" detection device\* is a viable point-of-care alternative to the anti-Xa or DTT assays as the stick distinguishes dabigatran from the anti-Xa inhibitors.<sup>6</sup> For those facilities that do not offer a rapid turnaround DOAC assay specific to the agent, clinicians must establish the DOAC identity and time of the most recent dosage by history before establishing treatment.<sup>7</sup> Healthcare systems shall collaborate with the laboratory medicine service to develop strategies that ensure efficacy and stewardship of reversal agents.<sup>8</sup>

\*Off-label or research use only.

## How This List Was Created (1–4)

The American Society for Clinical Pathology (ASCP) list of recommendations was developed under the leadership of the ASCP Effective Test Utilization Steering Committee. This committee is chaired by an ASCP Past President and is comprised of subject matter and test utilization experts across the fields of pathology and laboratory medicine. The committee considered a list of possible recommendations compiled as the result of a survey administered to Society members serving on ASCP's many commissions, committees and councils. In addition, an announcement was made to ASCP's Advisory Board seeking suggestions for possible recommendations to promote member involvement. The laboratory tests targeted in our recommendations were selected because they are tests that are performed frequently; there is evidence that the test either offers no benefit or is harmful; use of the test is costly and it does not provide higher quality care; and eliminating it or changing to another test is within the control of the clinician. Implementation of these recommendations will result in higher quality care, lower costs and a more effective use of our laboratory resources and personnel.

## How This List Was Created (5)

This recommendation was developed under the leadership of ASCLS's *Choosing Wisely* Committee and the ASCLS Board of Directors. The Committee examined numerous options based on evidence available. Subject matter experts from the ASCLS Scientific Assemblies reviewed, edited, and recommended approval of this recommendation, which was subsequently reviewed and approved by the ASCLS Board of Directors.

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### About the ABIM Foundation

The mission of the ABIM Foundation is to advance medical professionalism to improve the health care system. We achieve this by collaborating with physicians and physician leaders, medical trainees, health care delivery systems, payers, policymakers, consumer organizations and patients to foster a shared understanding of professionalism and how they can adopt the tenets of professionalism in practice.

To learn more about the ABIM Foundation, visit [www.abimfoundation.org](http://www.abimfoundation.org).



### About the American Society for Clinical Pathology

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The American Society for Clinical Laboratory Science (ASCLS) and its 9,000 clinical laboratory professional, student, and educator members in more than 50 state and regional constituent societies work to advance the expertise of clinical laboratory professionals who, as integral members of interprofessional healthcare teams, deliver quality, consumer-focused, outcomes-oriented clinical laboratory services through all phases of the testing process to prevent, diagnose, monitor and treat disease. The Society promotes high standards of practice by holding the profession accountable to a Code of Ethics, through dissemination of knowledge at educational programs and through publications; maintains a supportive community to advocate on behalf of current and future laboratory professionals; and provides laboratory professionals a voice to legislators and regulators through collective, grassroots efforts.

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Clinical Laboratory Science

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1

### Do not routinely send urine for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* (CT/NG) testing from females if vaginal swab collection is possible.

Nucleic acid amplification testing (NAAT) for CT/NG is standard of care for testing adults and has largely replaced culture. Vaginal swabs are the preferred single specimen for screening and diagnosis of CT/NG by NAAT providing 5% to >10% increased sensitivity compared to urine for females; testing multiple specimens (vaginal, endocervical, and urine) can further increase sensitivity. When vaginal collections are not possible due to the setting, test or collection device shortages, or very strong patient preference, *first-void* urine can be considered as a non-invasive alternative.

2

### Do not perform heterophile antibody (monospot) testing to diagnose acute EBV infection in children less than 5 years of age.

Approximately 40% of children under 5 years do not develop heterophile antibodies following primary EBV infection. If the heterophile is the only test ordered, the diagnosis may be missed. The U.S. Centers for Disease Control and Prevention has advised against heterophile testing in this age group due to lack of specificity and potential for false negative results. Testing in this age group should be a panel of EBV-specific serologic antibody immunoassays for viral capsid antigen (VCA) IgM and IgG and Epstein-Barr nuclear antigen (EBNA).

3

### Do not test for influenza unless the patient is symptomatic and the result will influence clinical management and decision making.

The United States Centers for Disease Control and Prevention (CDC) National Center for Immunization and Respiratory Diseases (NCIRD) recommends when influenza is circulating in the community that hospitalized patients with influenza indications undergo influenza testing, and the Infectious Disease Society of America (IDSA) recommends rapid influenza molecular assays or reverse transcriptase polymerase chain reaction [RT-PCR] testing for greatest diagnostic certainty. The NCIRD indications include typical influenza symptoms, atypical presentations, complications, and admission status.

Three scenarios to consider:

1. Perform molecular testing if a patient has signs and symptoms suggestive of influenza, including an atypical clinical presentation, or findings suggestive of complications associated with influenza and is being admitted to the hospital.
2. Perform molecular testing if a patient has signs and symptoms suggestive of influenza, and is not being admitted to the hospital, but the result will influence clinical management.
3. If a patient is not symptomatic, then influenza testing is probably not indicated.

4

**Do not prescribe immune suppressive agents for suspected autoimmune hepatitis (AIH) without first excluding hepatotropic virus infections (e.g., viral hepatitis A, B, and C). Viral hepatitis may mimic AIH, both serologically and histologically, features that may resolve with direct-acting antiviral (DAA) treatment.**

Viral hepatitis, including that caused by hepatitis A, B, and C, can lead to development of autoantibodies (e.g., antinuclear, anti-smooth muscle actin (SMA)/F-actin, liver–kidney microsomal type 1 (LKM-1), soluble liver antigen (SLA), and immunoglobulin G (IgG)) in approximately 50% of cases. The autoantibody profile in patients with chronic HCV may cause clinical suspicion of concurrent AIH and may prompt unnecessary liver biopsies and/or immune suppressive treatments. HAV, HBV, and HCV, may have similar histologic and clinical features including frequent plasma cells, elevated transaminases and may lead to cirrhosis. However, treatment is markedly different. Treatment of HCV is with interferon (IFN)-free or DAA therapy, achieving sustained viral responses (SVR) in most cases and has been shown to eliminate both clinical and histologic features of AIH. Therefore, patients with chronic hepatitis C who have serum markers and/or histologic features of AIH should first be treated with DAA in most cases.

5

**Don't order tissue transglutaminase IgG antibody or Deamidated Gliadin Peptide (DGP) antibodies (IgG or IgA) in the initial screening for Celiac Disease.**

Tissue transglutaminase IgA antibody (anti-tTG IgA) is the recommended first-line screening test for celiac disease because it provides the best diagnostic sensitivity and specificity. Serum IgA should also be included to detect IgA deficiency. Tissue transglutaminase IgG antibody (anti-tTG IgG) or deamidated gliadin peptide antibodies (IgG or IgA) could be appropriate as reflex tests in specific situations based on initial findings although they have less specificity than the tissue transglutaminase IgA antibody. In particular, Deamidated Gliadin Peptides result in a higher false positive rate that can lead to further unnecessary testing and/or endoscopy.

## How This List Was Created (1–2)

The American Society for Microbiology's (ASM) list was developed under the leadership of the ASM's Clinical and Public Health Microbiology Committee. The subject matter experts who identified the list and formulated the recommendations are laboratory directors at academic, commercial and public health laboratories and test utilization experts across the fields of microbiology and laboratory medicine. They worked together to identify a list of diagnostic and management decisions that have resulted in misuse of laboratory studies and resources.

In this submission, two statements were written to address the most common clinical microbiology laboratory test misconceptions. They consist of diagnostic tests or treatments that are commonly ordered, expensive and have no evidence to illustrate its value and in some cases, may be potentially harmful to the patient. The recommendations, if instituted, would result in higher quality care, lower costs, and more effective use of our laboratory resources and personnel. The experts involved in the new 2022 recommendations are James Dunn, Laura Filkins, Omai Garner, Elizabeth Palavecino and Preeti Pancholi.

## How This List Was Created (3–4)

These ASCLS recommendations were developed under the leadership of ASCLS's Choosing Wisely Committee and the ASCLS Board of Directors. The Committee examined numerous options based on evidence available. Subject matter experts from the ASCLS Scientific Assemblies reviewed, edited, and recommended approval of these recommendations, which were subsequently reviewed and approved by the ASCLS Board of Directors.

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## Sources

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### About the American Society for Microbiology

The American Society for Microbiology is the largest single life science society, composed of 30,000 scientists and health professionals. ASM's mission is to promote and advance the microbial sciences.

ASM advances the microbial sciences through conferences, publications, certifications and educational opportunities. It enhances laboratory capacity around the globe through training and resources. It provides a network for scientists in academia, industry and clinical settings. Additionally, ASM promotes a deeper understanding of the microbial sciences to diverse audiences.

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