

Using Diagnostic Tests to Inform Better Care, Save Lives and Fight Antibiotic Resistance

A Factsheet for Health Care Professionals



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The widespread use of antibiotics and the development and spread of antibiotic resistance genes has led to a sharp increase in drug-resistant infections that are changing the practice of modern medicine. Diagnostic tests, which can help identify the cause of an infection, are important tools in improving prescribing decisions, reducing antibiotic use and potentially slowing the spread of antibiotic resistance. Diagnostic tests continue to evolve and are providing more information in a shorter period of time, thereby allowing better clinical decision-making to improve patient care and combat antibiotic-resistant bacteria. This fact sheet is intended to help healthcare providers learn more about currently available diagnostic tests and how they can be used to improve patient care and reduce inappropriate antibiotic use.

Antibiotics Aren't Always the Answer and Have Hidden Costs

Antibiotics are some of the most widely used medicines, but they are not always the optimal patient management strategy. In fact, up to 50 percent of all antibiotics prescribed in outpatient settings are either unnecessary or are not effective as prescribed.¹ Prescribing antibiotics without conducting a test to ensure they are necessary has many hidden costs, including an increased risk of antibiotic-related adverse drug events such as drug allergy and increased risk of *Clostridium difficile* infection. In fact, antibiotics are the most commonly implicated drugs among children and adolescents visiting emergency departments for an adverse drug event.² Finally, using antibiotics unnecessarily or inappropriately can also drive the development of antibiotic-resistant bacteria that can significantly complicate management of infectious diseases ranging from minor skin and urinary tract infections to sepsis.

Diagnostic Tests Help Take the Guess Work Out of Medicine

Diagnostic tests provide critical insights at every stage of medical care—prevention, diagnosis, prognosis, treatment and successful management of almost all health conditions. However, despite the availability of a variety of rapid and accurate tests for infectious diseases, antibiotics are often



To see the full breadth of FDA approved or cleared diagnostics tests that are currently available please visit: <https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm>.

prescribed empirically, resulting in high rates of unnecessary or ineffective prescribing. The right diagnostic tests can help providers make a more informed decision and provide better care. Diagnostic tests can help determine whether infections are caused by a virus, bacteria, fungus, or parasite—so providers can distinguish between those infections that require antibiotic treatment and those that do not. These tests can also help determine when to stop antibiotics. Other tests provide information on an organism's resistance profile so doctors know which antibiotic (narrow-spectrum or when necessary, broad spectrum) will be most effective. Additionally, diagnostic tests enable effective disease surveillance and outbreak monitoring, and inform infection control actions to help prevent the spread of resistant organisms. When used appropriately, diagnostics tests can substantially improve care and help slow the development and spread of antibiotic resistant microorganisms.

Know the Different Types of Diagnostic Tests

Although there are more than 4,000 different diagnostic tests available today³ in the United States, the number focused on diagnosing infections is much more limited. Depending on their regulatory status and intended use, they can be performed in central laboratories, satellite laboratories and in various healthcare clinics. Since the availability of diagnostic tests vary from setting to setting, please see page three for some examples of common infections and diagnostic tests that are available in the U.S.

What You Can Do

You can help preserve the efficacy of antibiotics:

- Talk to your laboratories to determine what diagnostic tests are available in your hospital, (office, etc.), the usual turn around times of results, and the strengths and limitations of those assays
- Use diagnostic tests to inform treatment decisions, prescribing practices, and guide infection control decisions
- Learn more about available diagnostic tests and best practices that may not be in your laboratory but available through reference laboratories
- Support antibiotic stewardship and hospital/clinic infection control programs
- Explain to patients the importance of only taking an antibiotic when necessary
- Negotiate with health insurance companies for reimbursement of diagnostic tests based on fair-market rates
- Ask policymakers and private investors to invest in the development of diagnostic tests

Diagnostic tests are an integral component of health care and an important part of the fight against antibiotic resistance. The increased appropriate use of currently available diagnostic tests and the development of innovative, rapid and highly informative diagnostic tests are critical if we are to protect antibiotics from being obsolete. ■

Presenting Condition

Examples of Tests Available

PCR = polymerase chain reaction • Other NAAT = nucleic acid amplification test

Diarrhea	<ul style="list-style-type: none"> • Multiplex (i.e., multiple pathogen) gastrointestinal PCR and NAAT panels • <i>C. difficile</i> toxin gene PCR, NAAT, or antigen detection • Bacterial culture from stool • Individual viral pathogen PCRs (norovirus, rotavirus) • Shiga toxin latex agglutination assay • Cryptosporidium and Giardia antigen detection; microscopy
Respiratory symptoms	<ul style="list-style-type: none"> • Multiplex respiratory pathogen PCR panels • PCR for influenza/RSV • Individual PCR assays for bacterial pathogens (i.e. <i>Mycoplasma pneumoniae</i> PCR, <i>Bordetella pertussis</i>) • PCR for <i>Mycobacterium tuberculosis</i> and rifampin resistance detection • Urinary <i>Legionella</i> antigen assay • Bacterial, viral, fungal and mycobacterial culture • Antigen detection for viral pathogens (flu, RSV) • Host biomarkers (e.g., procalcitonin, CRP)
Urinary symptoms	<ul style="list-style-type: none"> • Urinalysis (leucocyte esterase, nitrate) • Bacterial culture and susceptibility testing
Skin/ soft tissue infection	<ul style="list-style-type: none"> • Bacterial, fungal and mycobacterial culture • Molecular diagnostic test to detect MRSA/MSSA in abscesses
Sexually transmitted infection	<ul style="list-style-type: none"> • PCR and NAATs for <i>Neisseria gonorrhoeae</i> and <i>Chlamydia trachomatis</i> • PCR or NAAT for <i>Trichomonas vaginalis</i> or antigen detection • Herpes simplex PCR or viral culture • PCR and DNA probes tests for bacterial vaginosis and vaginitis, Gram stain (Nugent score) • Dark field microscopy (syphilis) • Bacterial culture
Suspected meningitis or encephalitis	<ul style="list-style-type: none"> • Multiplex meningitis/encephalitis PCR panel (viral, bacterial, fungal) • PCR for enterovirus • Bacterial, fungal, viral, and mycobacterial culture • Cryptococcal antigen assay • Individual pathogen PCR assays (e.g., HSV, enterovirus, West Nile Virus)
Suspected sepsis or bacteremia	<ul style="list-style-type: none"> • Bacterial and fungal blood cultures • Multiplex bacterial/fungal and resistance gene PCR/NAAT panels performed on positive blood culture bottles • PCR for MRSA/MSSA from positive blood culture bottles • PCR for <i>Candida</i> species directly from blood • MALDI-TOF mass spectrometry for microbial identification performed on isolates from positive blood culture bottle • In situ hybridization or cellular analysis optical system for microbial identification performed on isolates from positive blood culture bottles • Antimicrobial susceptibility test panels (manual and automated) for susceptibility and MIC results • Host biomarkers (e.g., procalcitonin, CRP)

How Diagnostic Tests Help Combat Antibiotic Resistance



Improve patient care by optimizing antibiotic use



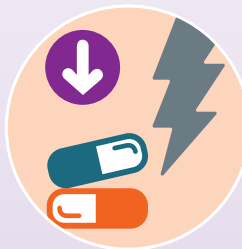
Decrease overall medical costs through shorter length of stays & optimized infection control programs



Help ensure doctors prescribe the correct antibiotic at the right time & dose



Improve judicious use of antibiotics



Reduce misuse of antibiotics



Identify drug-resistant organisms to enable patient isolation, decontamination, & reduce spread of infections

Endnotes

- 1 Antibiotic Resistance Threats in the United States, 2013, Centers for Disease Control and Prevention. <https://www.cdc.gov/drugresistance/threat-report-2013/>.
- 2 US Emergency Department Visits for Outpatient Adverse Drug Events, 2013–2014, *JAMA*, November 2016. <http://jamanetwork.com/journals/jama/article-abstract/2585977>.
- 3 AdvaMedDX, Diagnostic Innovation & Value. <https://dx.advamed.org/diagnostics-policy/innovation-value>.

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**ANTIBIOTIC
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