



Diagnostic Stewardship Toolkit



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Diagnostic Stewardship Toolkit Purpose

This toolkit is intended for multidisciplinary healthcare teams, which include clinical laboratory professionals. It can help your organization form diagnostic stewardship teams and apply the principles of diagnostic stewardship. This toolkit also can help diagnostic stewardship teams save time and healthcare resources. Additionally, it can help patients receive rapid and accurate diagnoses.

Clinical laboratory professionals are essential to diagnostic stewardship teams. Studies suggest diagnostic error rates are lower in clinical laboratories than in other healthcare settings.¹ Testing errors in the clinical laboratory setting continue to drop due to quality assessments and regulations. Clinical laboratory professionals can help determine if a diagnostic error affected clinical decision-making. Actively preventing diagnostic errors and reducing patient harm supports patient safety improvements.



A diagnostic stewardship team including laboratory professionals discusses ways to improve patient care.

Diagnostic Stewardship Introduction

Diagnostic stewardship supports ordering the right test for the right patient at the right time. This process leads to the right diagnostic actions to improve patient outcomes.

Diagnostic stewardship uses a multidisciplinary team approach to optimize clinical testing. Testing helps guide patient care. Inappropriate testing or not ordering appropriate tests may lead to patient harm. Diagnostic stewardship focuses on reducing patient harm by informing clinical decisions. Process changes aim to reduce diagnostic errors by improving the use and interpretation of tests.



The Clinical Laboratory's Role in Diagnostic Stewardship

Drawing on a clinical laboratory's expertise promotes diagnostic excellence. Working with clinicians to better understand laboratory testing supports diagnostic stewardship. Guiding clinical decisions and educating providers can reduce diagnostic errors. In addition, electronic health record tools support test ordering and reporting. For example, laboratory test ordering menus can be customized. A clinical laboratory can provide consultation during test selection and test result interpretation. Testing often involves various laboratory specialties and other diagnostic services. Collaboration among care teams can enhance the accuracy of a diagnosis.

Diagnostic Challenges



Diagnostic stewardship prioritizes reducing misdiagnoses to improve clinical care. Misdiagnoses can occur when an incorrect test is ordered. Also, diagnostic errors occur with inaccurate, incomplete, or misinterpreted test results. A false-positive diagnosis may lead to patient overtreatment. A delayed or missed diagnosis may lead to patient

undertreatment. Three key drivers of laboratory services affect patient outcomes: ordering tests, retrieving results, and interpreting results. Care teams could consider the test result in context with the patient's symptoms and any additional test results.

Of surveyed primary care physicians, almost 15% were unsure which test to order. Also, about 8% of physicians were unsure how to interpret test results.² One challenge during test ordering is confusing test names. Test selection also may be difficult when a patient's clinical symptoms overlap across conditions. Providing testing algorithms could suggest when to use specific tests.

Benefits of Diagnostic Stewardship

Accurate and timely diagnoses positively affect patient care. Diagnostic stewardship aims to improve patient diagnosis, treatment plans, and disease monitoring. A definitive diagnosis can reduce unnecessary testing, inappropriate care, and hospital stay times. Effective diagnostic stewardship helps save healthcare resources. Also, diagnostic stewardship paired with antibiotic stewardship promotes appropriate antibiotic treatment. Appropriate testing and treatment improve patient outcomes.



Diagnostic Stewardship Principles

Diagnostic stewardship is a field of practice intended to optimize clinical testing. The principles are based on reducing diagnostic errors to improve patient care. Diagnostic stewardship teams identify testing process interventions that help inform clinical decisions. Interventions are often modifications to ordering or reporting diagnostic tests. Diagnostic stewardship teams strategize how to improve patient diagnosis by preventing errors. They also may discuss improving diagnosis by evaluating new or additional tests to be added to the laboratory test menu.



Engage a collaborative diagnostic stewardship team.

Diagnostic stewardship teams involve multiple disciplines. Disciplines may include laboratory medicine, pharmacy, nursing, and treating clinicians. Teams are encouraged to consider the tests that will most affect patient care. For example, hospitals could prioritize best practices for blood cultures, urine cultures, respiratory cultures, and *C. difficile* bacteria testing. Diagnostic tests are not limited to microbiology and may include specialties such as chemistry and imaging services.

Key steps to consider when implementing a new diagnostic stewardship intervention are listed in Appendix A.³

Total Testing Process



Diagnostic stewardship aims to improve patient care by optimizing the total testing process. The total testing process serves as a guide for clinical testing cycles. It involves all steps in each testing phase. Activities include ordering tests in the pre-analytic phase; performing tests in the analytic phase; and reporting results in the post-analytic phase.

Diagnostic stewardship interventions can occur at any stage of the total testing process. An intervention is an action designed to improve diagnostic testing and patient care. Effective interventions better inform clinical decisions. Diagnostic stewardship can support the laboratory in the pre-analytic and post-analytic phases of testing with interventions that improve patient care. Interventions can be built into both the patient care and laboratory setting workflows.



Consider the steps in the total testing process listed in Appendix B when planning a diagnostic stewardship intervention.^{4,5}

Plan a diagnostic stewardship intervention within the total testing process.

Total Testing Process: Pre-analytic Phase

Diagnostic stewardship focuses on improving patient care by reducing diagnostic errors. Studies suggest most diagnostic errors occur in the pre-analytic phase of the total testing process.⁵ The pre-analytic phase includes any steps before a patient specimen is tested.

When selecting a test, consider the pretest probability of a diagnosis. Pretest probability is the likelihood that a patient has an infection or condition before testing occurs. A high pretest probability means a positive test result is likely a true-positive result. A low pretest probability means a positive test result is more likely a false-positive result.

Use care when collecting all patient specimens, especially those collected from non-sterile sites such as wounds. A wound culture may not distinguish bacterial colonization or presence from an active infection.

Procedures help guide best practices during each step of the total testing process. Common pre-analytic procedure steps are listed in Appendix C.⁶

Diagnostic laboratories should establish procedures that follow Clinical Laboratory Improvement Amendments (CLIA) regulations.



Diagnostic Stewardship and Antibiotic Stewardship

Stewardship programs focus on improving the value of healthcare services. Diagnostic stewardship and antibiotic stewardship complement each other to provide better patient care.

Antibiotic stewardship promotes optimal antibiotic use to improve patient outcomes. Appropriate antibiotic treatment can reduce antibiotic resistance.

Recent studies have reviewed how diagnostic errors can influence antibiotic overuse and misuse.⁷ Since diagnostic stewardship is an approach to reduce diagnostic errors, it is an important part of antibiotic stewardship efforts.

Antibiotic stewardship has traditionally focused on collaboration among clinicians and pharmacists. Diagnostic stewardship also includes the microbiology laboratory and may include other laboratory and hospital services.

Diagnostic stewardship and antibiotic stewardship teams play important roles in patient care, as shown in Appendix D.⁷



Engage diagnostic stewardship and antibiotic stewardship teams to work together.

Appendix A: Diagnostic Stewardship Intervention Checklist

Use this checklist as a guide when developing a new diagnostic stewardship intervention.³

- Define a clear goal.**
 - Choose a specific goal aiming to improve patient diagnosis.
 - Determine if the goal is measurable and realistic.
 - Recognize situations that may adjust the goal timeline.

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- Involve relevant team members such as:**
 - Clinical laboratory and pathology experts.
 - Antibiotic stewardship and infection control experts.
 - Information technology and administrative support.
 - Hospital leadership.
 - Radiology professionals.
 - End users such as clinicians and nurses.
 - Patients and caregivers as applicable.



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- Seek hospital or unit leadership support to:**
 - Identify and dedicate resources such as workforce and equipment.
 - Develop a statement of support to encourage end-user acceptance.

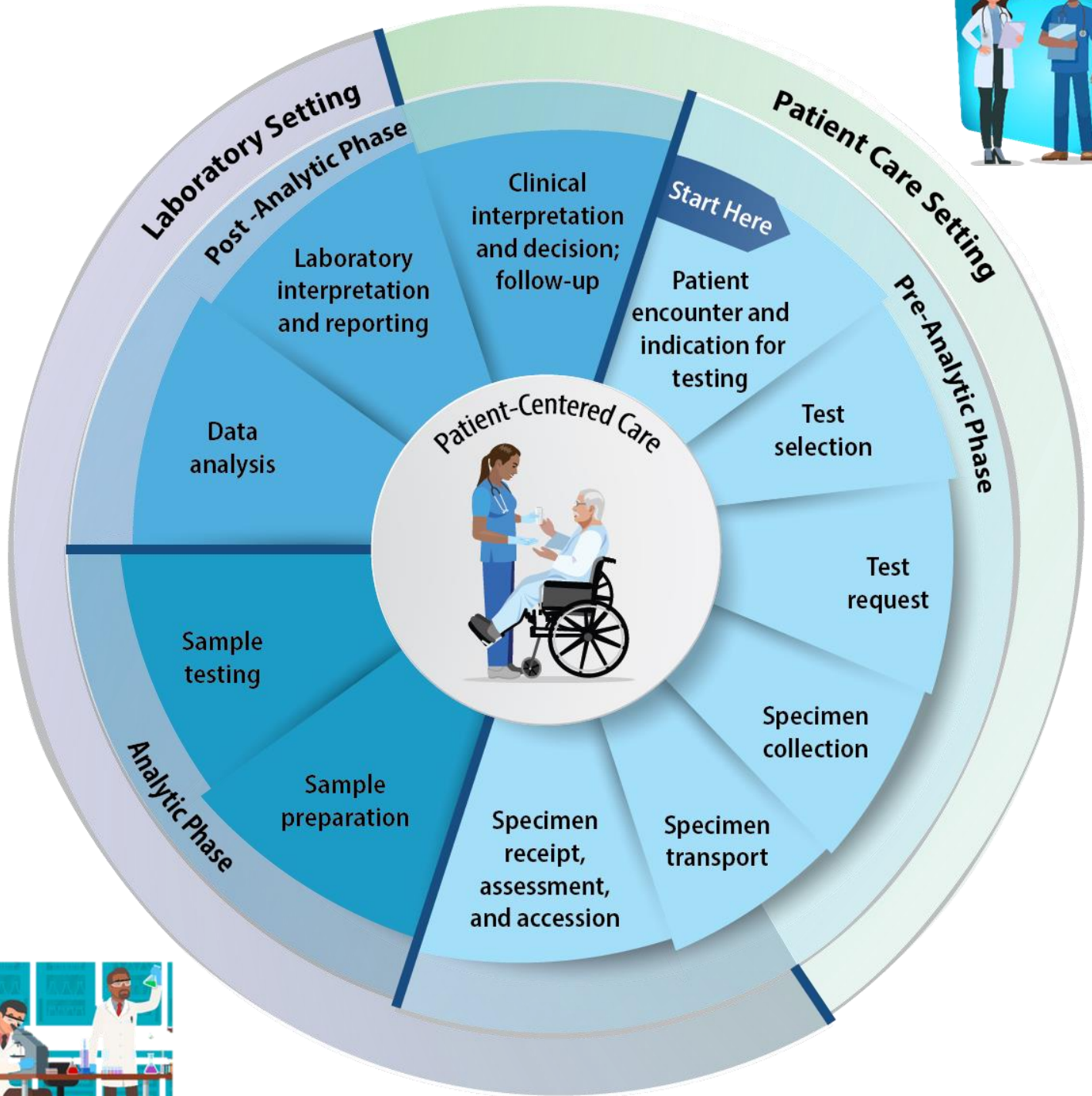
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- Define measures to track the positive or negative effects of the intervention.**

Refer to data from electronic health records or laboratory information systems such as:

 - Testing trends such as type, amount used, and turnaround time.
 - Patient outcomes and length of hospital stay.
 - Saved healthcare resources such as testing supplies.

Appendix B: Total Testing Process Flowchart

Use this flowchart as a guide to understand the total testing process in patient-centered care.^{4,5}



Appendix C: Pre-analytic Phase Practices Checklist

Use this checklist as a guide to help establish best practices during the pre-analytic phase.⁶

- Identify the correct patient.
 - Ensure patient information on the authorized test order is correct.
 - Match the correct patient and specimen to the test order.

- Collect the patient specimen(s).
 - Ensure the specimen type and amount are correct.
 - Take care to avoid a contaminated or unacceptable specimen.

- Label and store each specimen collection container.
 - Apply clear and correct labels as soon as a specimen is collected.
 - Ensure labels have the patient's name and a unique patient identifier such as the patient's date of birth.
 - Follow specific specimen storage and preservation procedures.

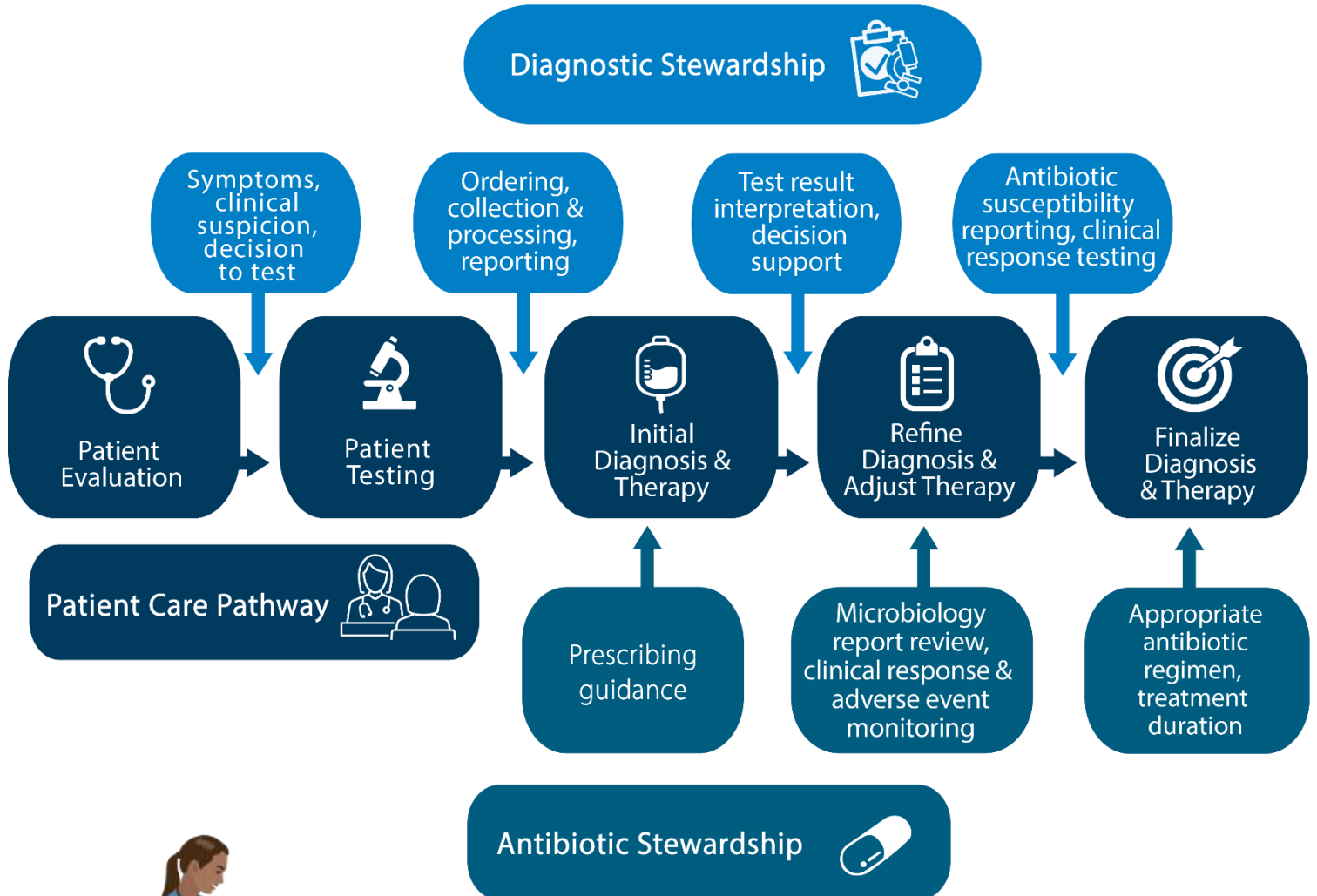
- Transfer the patient specimen to the laboratory setting.
 - Seal the primary specimen collection container in a secondary leak-proof container.
 - Maintain proper specimen temperature as determined by the laboratory.
 - Follow packing and shipping procedures if shipping.

- Follow laboratory-specific specimen acceptance and rejection criteria.
 - Document the date and time a specimen is received by the laboratory.
 - Laboratory specimen rejection criteria may include:
 - Poor condition upon arrival.
 - Low volume.
 - Incorrect specimen type.
 - Incorrect labeling.
 - Incorrect temperature.
 - Transfer delays.



Appendix D: Diagnostic Stewardship and Antibiotic Stewardship Flowchart

Use this flowchart as a guide to understand the roles of diagnostic stewardship and antibiotic stewardship during patient diagnosis and treatment. ⁷



Glossary

Analytic: the phase of the total testing process that includes performing a diagnostic test in the laboratory.

Antibiotic stewardship: promotes optimal antibiotic use to improve patient outcomes.

Diagnostic error: delayed, missed, and wrong diagnoses that can lead to patient harm.

Diagnostic stewardship: ordering the right tests for the right patient at the right time to provide information necessary to optimize clinical care.

Diagnostic stewardship intervention: often modifications to ordering or reporting diagnostic tests.

Diagnostic test: a device or process performed to aid in the detection or clinical diagnosis of a disease or condition.

Multidisciplinary team: a collaborative group of professionals with different skills and training backgrounds.

Optimize: Improve the overall performance of a process.

Post-analytic: the phase of the total testing process that includes reporting of diagnostic test results, as well as evaluation, interpretation, and intervention.

Pretest probability: estimated probability of a person having the disease before a diagnostic is performed.

Pre-analytic: the phase of the total testing process that includes test ordering and specimen collection, transportation, and preparation.

Sample: a group of multiple specimens processed during testing.

Specimen: an individual piece to be tested; in this case from a patient.

Total testing process: the ordering, collection, transportation, preparation, performance, reporting, evaluation, and interpretation of diagnostic tests.

References

1. Hammerling JA. A review of medical errors in laboratory diagnostics and where we are today. *Laboratory Medicine*. 2012;43(2):41-44. <https://doi.org/10.1309/LM6ER9WJR1IHQAUY>
2. Hickner J, Thompson PJ, Wilkinson T, et al. Primary care physicians' challenges in ordering clinical laboratory tests and interpreting results. *J Am Board Fam Med*. 2014;27(2):268-274. <https://doi.org/10.3122/jabfm.2014.02.130104>
3. Fabre V, Davis A, Diekema DJ, et al. Principles of diagnostic stewardship: A practical guide from the Society for Healthcare Epidemiology of America Diagnostic Stewardship Task Force. *Infect Control Hosp Epidemiol*. 2023;44(2):178-185. <https://doi.org/10.1017/ice.2023.5>
4. Lubin IM, Astles JR, Bunn JD, et al. The clinical laboratory is an integral component to health care delivery: an expanded representation of the total testing process. *Am J Clin Pathol*. 2023;160(2). <https://doi.org/10.1093/ajcp/aqad038>
5. Lubin IM, Astles JR, Shahangian S, et al. Bringing the clinical laboratory into the strategy to advance diagnostic excellence. *Diagnosis*. 2021;8(3):281-294. <https://doi.org/10.1515/dx-2020-0119>
6. The Federal Register. *Medicare, Medicaid, and CLIA programs; laboratory requirements relating to quality systems and certain personnel qualifications. Condition: Preanalytic systems*. January 24, 2003. Accessed March 28, 2024. <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493/subpart-K/subject-group-ECFR5f8f0b6639946fd>
7. Ku TSN, Mohajer MA, Newton JA, et al. Improving antimicrobial use through better diagnosis: the relationship between diagnostic stewardship and antimicrobial stewardship. *Infect Control Hosp Epidemiol*. 2023;44(12):1901-1908. <https://doi.org/10.1017/ice.2023.156>

Additional Resources

1. Curren EJ, Lutgring JD, Kabbani S, et al. Advancing diagnostic stewardship for healthcare-associated infections, antibiotic resistance, and sepsis. *Clin Infect Dis*. 2022;74(4):723-728. <https://dx.doi.org/10.1093/cid/ciab672>
2. Claeys KC, Johnson MD. Leveraging diagnostic stewardship within antimicrobial stewardship programmes. *Drugs Context*. 2023;12:2022-9-5. <https://dx.doi.org/10.7573/dic.2022-9-5>
3. Hueth KD, Prinzi AM, Timbrook TT. Diagnostic stewardship as a team sport: interdisciplinary perspectives on improved implementation of interventions and effect measurement. Review. *Antibiotics*. 2022;11(2):15. <https://dx.doi.org/10.3390/antibiotics11020250>
4. Morgan DJ, Malani PN, Diekema DJ. Diagnostic stewardship to prevent diagnostic error. *JAMA*. 2023;329(15):1255-1256. <https://dx.doi.org/10.1001/jama.2023.1678>
5. Morgan DJ, Malani P, Diekema DJ. Diagnostic stewardship – leveraging the laboratory to improve antimicrobial use. *JAMA*. 2017;318(7):607-608. <https://dx.doi.org/10.1001/jama.2017.8531>
6. Passiment E, Meisel JL, Fontanesi J, et al. Decoding laboratory test names: a major challenge to appropriate patient care. *J Gen Intern Med*. 2013;28(3):453-458. <https://doi.org/10.1007/s11606-012-2253-8>
7. Tchou MJ, May S, Holcomb J, et al. Reducing point-of-care blood gas testing in the intensive care unit through diagnostic stewardship: a value improvement project. *Pediatr Qual Safety*. 2020;5(4):e284. <https://dx.doi.org/10.1097/pq9.0000000000000284>