News & Stories

Current Challenges in Clinical Diagnostic Testing

As the demand for diagnostic tests rises globally, laboratories are seeking out new solutions to maximize productivity and reduce costs.

Text: Linda Brookes

Daily challenges in clinical diagnostic testing.

Worldwide, clinical diagnostic laboratories are facing huge technical and financial challenges and are looking to innovations to maximize productivity while also helping to reduce costs. Advances in diagnostic testing, which have led to improved techniques and an expanding number of available tests, as well as the growth in the aging population, increased management of chronic diseases, access to care, and public interest in in vitro diagnostics (IVD), have all led to an increased demand for tests. Meantime, the organizations that purchase the tests, such as hospital chains, networks, and associations, are facing reduced budgets and are looking to cut down the number of tests carried out wherever possible.

Integrating and Streamlining Testing

With consolidation and regionalization of hospitals and healthcare organizations, there is increasing demand among integrated health networks for greater centralization of diagnostic testing in order to streamline workflows and steer better healthcare information to professionals. The core laboratory, optimized for highly automated, routine lab tests, primarily in clinical chemistry, immunology and hematology, is viewed as a key solution to addressing these growing needs. However, core labs also face the challenge of becoming as efficient and productive as possible without compromising on quality. Many core labs are looking to improve testing efficiency and better manage resources by upgrading to total laboratory automation (TLA) i.e., automation of pre-analytical, analytical, and post-analytical operations. Although TLA can be challenging to plan and implement, it is particularly suited to laboratories that conduct a wide spectrum of highly automated testing coupled with sophisticated laboratory information systems. TLA avoids the duplication, delays, and waste that can occur with task targeted automation. New platforms that synchronize expanding menus of tests and can be connected to automation can also be used as standalone systems.

The challenge for the laboratory professional is to decide on what kind and extent of automation is most appropriate for a given facility, and leverage the full capability of automation to drive quality and production improvement.

Testing Outside the Core Laboratory

With continued innovation and investment in diagnostic technique, important advances have been made in molecular diagnostics, which are becoming the standard for oncology and infectious disease, next generation sequencing (NGS), and genome-wide association studies (GWAS). In parallel with the process of centralization of the laboratory tests, point of care (POC) technologies are moving some laboratory tests closer to the patient, obviating the need to transport

samples to a central laboratory and enabling faster return of results. These tests, where available, are often preferred by physicians and patients, but despite their popularity, they are not all more cost-effective on a per-test basis, and the results of some, for example international normalized ratio (INR), may be less accurate than the results of clinical laboratory tests that remain the reference standard.[1]

Harmonization of Lab Test Results

A key responsibility of laboratory professionals is the definition and communication of critical laboratory results. Reported variations between procedures and policies used by different laboratories underline the need for harmonization of tests to allow timely and reliable communication of critical results to clinical personnel responsible for patient care.

Laboratory practice groups must collaborate with clinical and scientific organizations, laboratory test manufacturers, and accreditation and regulatory agencies to identify analyses that need improved harmonization and stimulate and sustain standardization initiatives in support of clinical practice guidelines. Harmonization has been achieved for a few laboratory tests, such as those for cholesterol, glucose, and hemoglobin A1c, which has led to improved outcomes and reduced costs in the diagnosis and treatment of heart disease and diabetes.[1] [2] However, many tests lack a reference measurement procedure that will allow standardization and universally accepted protocols must be developed in order to harmonize these tests.

Avoiding Inappropriate Testing

Although laboratory testing accounts for only about 3 to 5 percent of healthcare spending [3] healthcare organizations are under pressure to cut costs by reducing the volume of inappropriate, unnecessary, redundant, or obsolete tests, which are estimated to account for as many as 21 percent of tests ordered.[4] Laboratory professionals are having to become more involved in auditing, monitoring, and improving the appropriateness of test requests through increased collaboration with clinicians [5] and helping to increase their knowledge of test use.[6]

Future Directions

Current advances in clinical diagnostic testing can present laboratory teams with opportunities in upgrading and adopting new technologies and providing new services. But as well as reducing costs, increased automation and consolidation of different analytic systems will contribute to more productivity, faster turnaround time (TAT), and better quality of testing, as well as freeing up laboratory professionals from routine tasks to focus on more challenging responsibilities. ●

Linda Brookes MSc, is a freelance medical writer and editor who divides her time between London and New York, working for a variety of clients in the healthcare and pharmaceutical fields.

Healthcare organizations are under pressure to cut costs by reducing the volume of inappropriate, unnecessary, redundant, or obsolete tests.

Atellica® Solution

The Atellica Solution[2] represents a new way to simplify automated core lab testing with flexible, automation-ready immunoassay and chemistry analyzers. It includes a bi- directional sample conveyance system that utilizes magnetic levitation technology allowing for speeds up to 10 times faster than conventional technologies. The Solution can be used as a stand-alone or connected to automation. It is scalable up to 10 components and more than 300 customizable configurations are available.

Atellica® Process Manager

The integration of IT solutions enable labs to streamline management of connectivity, data, inventory, processes, and clinical decision support. Atellica® Process Manager[3] is a process-management tool that helps lab simplify management of laboratory operations, enabling management of alerts, testing, and onboard inventory, all from one screen. By aggregating data of multiple instruments and offering remote control of connected systems, the solution eliminates the need for technicians to walk from system to system to monitor testing. Data analytics and visualization provide insight into day-to-day workflow so that further process efficiencies can be realized.

References

[1] Johnson AS. Point-of-care or clinical lab INR for anticoagulation monitoring: Which to believe? Clin Lab News. April 1, 2017. https://www.aacc.org/publications/cln/articles/2017/april/point-of-care-or-clinical-lab-inr-for-anticoagulation-monitoring-which-to-believe.

[2] Hoerger TJ, Wittenborn JS, Young W. A cost-benefit analysis of lipid standardization in the United States. Prev Chronic Dis. 2011;8:A136.

[3] Song Z, Safran DG, Landon BE, et al. Health care spending and quality in year 1 of the alternative quality contract. N Engl J Med. 2011;365:909-18.

[4] Zhi M, Ding EL, Theisen-Toupal J, et al. The landscape of inappropriate laboratory testing: a 15-year meta-analysis. PLoS One. 2013;8:e78962.

[5] Taylor JR, Thompson PJ, Genzen JR, et al. Opportunities to enhance laboratory professionals' role on the diagnostic team. Lab Med. 2017;48:97-103.

[6] Ferraro S, Panteghini M. The role of laboratory in ensuring appropriate test requests. Clin Biochem. 2017;50:555-61.

[1] DCA HbA1c test kit 10698915 (an aid to diagnose diabetes and identify patients at risk for developing diabetes) is not available for sale in the U.S. Product availability varies by country.

[2] Product availability varies by country.

[3] Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

The Siemens Healthineers Walpole Facility

Siemens Healthineers' key research and development and production facility for lab diagnostics in Walpole, Massachusetts, has begun a $300 million renovation and expansion. At the groundbreaking ceremony, attended by global management, local employees and politicians, including Massachusetts governor Charlie Baker, Siemens Healthineers confirmed that the latest expansion will increase the facility's capacity to deliver new products like the Atellica™ portfolio. The manufacturing, warehouse, office, and lab complex, originally built in 1979, currently employs around 700 people. The expansion potentially could double the size of the facility and add up to another 700 new high-tech jobs.

The statements by Siemens Healthineers customers described herein are based on results that were achieved in the customer's unique setting. Since there is no "typical" hospital and many variables exist (e.g., hospital size, case mix, level of IT adoption) there can be no guarantee that other customers will achieve the same results.