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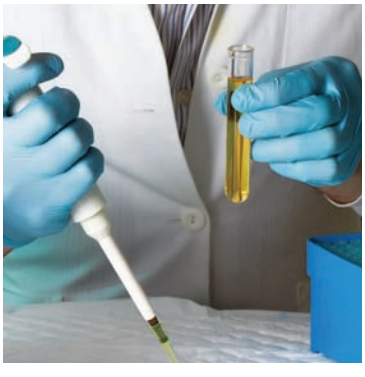

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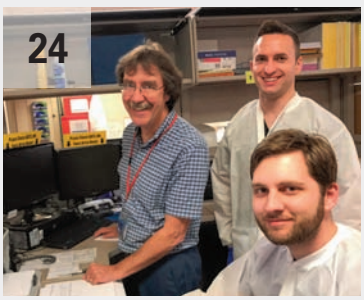

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Ignorance is bliss

By Lisa Moynihan
Editor

April 2019 marks the fifth year I've been involved in *MLO*'s Lab of the Year (LOY) contest. As an *MLO* "newbie" in 2015, I underestimated the vital role the laboratory plays in healthcare. Even after working for 15 years within the pharmaceutical trade, it became clear I'd been working in a silo, unaware of the bigger picture.

Today, thanks to *MLO*, I have a whole new respect and appreciation for the medical laboratory industry—especially in regard to my local healthcare system. From the phlebotomists that collect my blood at Quest, to the nurses who administer my Feraheme drip at Florida Cancer Specialists, to the Veracyte pathologists who analyze my liquid biopsies…the list goes on.

There are approximately 300,000 practitioners of clinical laboratory science in the United States.[1] A medical laboratory's chief concern is the diagnosis and treatment of patients. There are many medical symptoms that can be caused by very different illnesses, and often the true cause (and correct treatment) can only be determined by the lab. The news they bear is vital to accurate treatment. It may sound ignorant, but five years ago, when I was wearing my patient hat, I'd never really thought about the lab after I had left it. Diagnosis and treatment had always started and stopped with my physician.

Like every other consumer, I would begrudgingly forgo my morning coffee so I could get my fasting blood drawn in the early morning before work. I'd look the other way as my blood was drawn (I still do), gazing at the rainbow-colored tourniquets and wondering if I'd be left with a bruise and how soon I could escape the chair to get some food...blissfully unaware of what would happen to my tubes of blood after I left the facility.

Now, in its 44th year, Medical Laboratory Professionals Week, which takes place April 21-27, 2019, is an annual celebration of medical laboratory professionals and pathologists. *MLO's* annual LOY contest strategically coincides with this event every April (see page 16 for the 2019 LOY winners!). Unfortunately, the efforts of laboratory professionals often go unnoticed by the general public, as well as by the very institutions employing their services. With the public now demanding quality healthcare and professional accountability, organizations representing laboratorians have a responsibility to ensure that the public is well informed about their competency.

The American Society of Clinical Laboratory Professionals have some awareness materials publicly available (https://www.ascls.org/celebrate/125-scholarships-and-awards2/new-professional-of-the-year/101-new-professional-of-the-year), however who is responsible for educating the masses? Who else is creating and disseminating patient-directed materials that showcase what goes on behind the scenes of a laboratory? On a nationwide level? On an international level? Perhaps regular PSAs are needed from the FDA or the CDC?

The enormous challenge of public health education is one I will leave to those better equipped to do so. In the meantime, I will continue to strive to provide quality content on behalf of *MLO*, educate and be an advocate for myself and my immediate family, and remember to thank my local healthcare team for their continued dedication and hard work. #Lab4Life

REFERENCE

1. ASCLS. American Society of Clinical Laboratory Scientists. https://www.ascls.org/about-us/celebrate/125-scholarships-and-awards2/new-professional-of-the-year/101-new-professional-of-the-year. Accessed March 12, 2019.

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FAST FACTS

Obesity

Obesity is a common, serious, and costly disease. Following are some interesting statistics about obesity in the U.S.

93.3 million

adults were affected by obesity in 2015-2016.

13.7 million

children and adolescents were affected by obesity in 2015-2016.

$147 billion

was the estimated annual medical cost of obesity in 2008.

$1,429

is the additional medical cost obese individuals incur compared to those of normal weight.

112,000

deaths annually are attributable to obesity.

40 percent

of adults do not participate in any leisure-time physical activity.

100 pounds

more than an individual's ideal body weight or having a body mass index (BMI) of </= 40 characterizes severe obesity.

25 percent

of individuals affected by severe obesity were being treated for six or more obesity-related conditions in 2002.

• **Sources:** https://www.cdc.gov/obesity/data/childhood.html, https://www.obesityaction.org/get-educated/public-resources/obesity-statistics-fact-sheets/

Molecular diagnostics

BD complete molecular portfolio for gastrointestinal infection (GI) with new viral panel. BD (Becton, Dickinson and Company) announced the U.S. Food and Drug Administration (FDA) 510(k) clearance of its BD MAX enteric viral panel, a molecular diagnostic test for the direct qualitative detection and differentiation of enteric viral pathogens that cause viral gastroenteritis. The company now offers a broad suite of solutions for the detection of intestinal conditions of bacterial, viral, and parasitic origin, in clinically relevant, targeted panels.

Acute viral gastroenteritis can be contracted by virtually any patient and spread within close community settings such as daycare centers, nursing facilities, and cruise ships. Norovirus is the most common viral cause and accounts for 19 to 21 million cases of diarrheal illness annually in the United States, and 50 percent of all foodborne diarrheal outbreaks. Other viral causes include rotavirus, adenovirus, astrovirus, and sapovirus to varying degrees of prevalence. Diagnosing the underlying cause of diarrhea can play a critical role in patient management to isolate patients at risk of spreading infectious diarrhea to others and rule out other causes of infection in children, the elderly, or immunocompromised patients.

The BD MAX enteric suite of molecular tests for the detection of gastrointestinal bacteria, parasitic, or viral pathogens enable clinicians to perform targeted testing for patients based upon their symptoms and health history or exposure. This testing approach is supported by the Infectious Diseases Society of America (IDSA) guidelines. The BD MAX enteric viral panel is designed for targeted detection of the viral cause of infectious diarrhea symptoms in all care settings and can detect norovirus, rotavirus, adenovirus, human astrovirus, and sapovirus.

The enteric panels run on the BD MAX molecular system and can return results in less than 3.5 hours, dramatically shortening time to results over traditional test methods. This shortened time to results allows clinicians to more quickly understand the cause of the patient's illness.

Pharmacogenomic testing

Translational Software partners with Allscripts to provide pharmacogenomic testing for associates. Translational Software recently announced its partnership with Allscripts Healthcare Solutions, a practice management and electronic health record (EHR) technology company. The collaboration will provide free pharmacogenomic testing to all U.S.-based Allscripts associates.

When associates undergo a lengthy process of trial-and-error prescribing, employers suffer the cost as well. Pharmacogenomic testing can help provide personalized guidance to individuals on medication efficacy and dosage, which results in improving medication adherence, increasing worker productivity, and reducing work absenteeism. With studies demonstrating the cost-effectiveness of pharmacogenomic-informed treatment, Allscripts recognized the value of associate wellness, satisfaction, and engagement in their overall health.

Translational Software has partnered with the telehealth company PWN Health and Allscripts subsidiary 2bPrecise to automate a new end-to-end pharmacogenomic healthcare benefit program. The new program is run on a portal built by Translational Software, where associates can place an order. PWN approves the order and sends out a testing kit. Once the kit is sent back by the associate, it is then routed to a testing laboratory in the Translational Software network selected by Allscripts. The laboratory performs the test and sends the interpreted results back to the portal, where they are accessible by the associate. If an associate is interested in

counseling on how to interpret their results, PWN offers telehealth sessions with a healthcare professional.

Translational Software is building an ecosystem of laboratories, health professionals, independent software vendors, and employers to coordinate and deliver comprehensive, personalized care. Translational Software can help employers understand and deliver an evidence-based pharmacogenomic benefit to their associates through custom programs like this one.

Breast cancer

Older biologic age linked to elevated breast cancer risk. Biologic age, a DNA-based estimate of a person's age, is associated with future development of breast cancer, according to scientists at the National Institutes of Health (NIH). Biologic age was determined by measuring DNA methylation, a chemical modification to DNA that is part of the normal aging process. The study showed for every five years a woman's biologic age was older than her chronologic or actual age, known as age acceleration, she had a 15 percent increase in her chance of developing breast cancer. The study was published online in the *Journal of the National Cancer Institute*.

Scientists from the National Institute of Environmental Health Sciences (NIEHS), part of NIH, speculate that biologic age may be tied to environmental exposures. If so, it may be a useful indicator of disease risk. They used three different measures, called epigenetic clocks, to estimate biologic age. These clocks measure methylation found at specific locations in DNA. Researchers use these clocks to estimate biologic age, which can then be compared to chronologic age.

The researchers used DNA from blood samples provided by women enrolled in the NIEHS-led Sister Study, a group of more than 50,000 women in the U.S. and Puerto Rico. The study was specifically designed to identify environmental and genetic risk factors for breast cancer. The research team measured methylation in a subset of 2,764 women, all of whom were cancer-free at the time of blood collection.

Lead author Jacob Kresovich, PhD, suggests that using DNA methylation to measure biologic age may help scientists better understand who is at risk for developing cancer and other age-related diseases. This research is an example of epigenetics, a field that studies how biochemical processes turn individual genes on or off, without affecting the DNA sequence.

Assays

Grifols receives FDA approval for donor screening assay. Grifols, a producer of plasma-derived medicines and a developer of diagnostic solutions, announced that the FDA approved the Procleix Babesia assay, a qualitative assay for the detection of the ribosomal RNA from four Babesia species (B. microti, B. duncani, B. divergens, B. venatorum) in individual samples or up to 16 pooled lysed specimens from human donors, including donors of whole blood and blood components for transfusion.

The assay runs on the Procleix Panther system—a fully automated platform utilizing Nucleic Acid Testing (NAT) for blood screening. The FDA approval recognizes a successful multi-center clinical trial conducted under an Investigational New Drug (IND) study at the American Red Cross, Creative Testing Solutions, and Rhode Island Blood Center (an affiliate of the New York Blood Center, Inc.), in select areas of the U.S.

Babesia is a parasite that can be transmitted to humans by tick bites or through donated blood from Babesia-infected donors.

According to the Centers for Disease Control and Prevention (CDC), the highest numbers of Babesia infections occurred in Massachusetts, New York, Connecticut, Rhode Island, New Jersey, Maine, New Hampshire, Wisconsin, and Minnesota.

HPV

Incidents of vocal cord cancer are on the rise in children, teens and young adults under 30. Research has shown vocal cord cancer can be viral (HPV), and results of a brand-new study shows this link between HPV and cancer may growing in children, teens and young adults under 30 years of age.

This research investigation was performed by vocal surgeon, Dr. Steven Zeitels at Harvard Medical School (HMS) and Massachusetts General Hospital (MGH), with the strategic support of the patient non-profit Voice Health Institute (VHI).

This is the first institutionally-based investigation to demonstrate that vocal cord cancer is undergoing a dramatic epidemiological change showing young patients are now being diagnosed who do not have a history of smoking.

The general public is not aware of this epidemiologic transformation and remarkably, despite this trend, the American Academy of Otolaryngology Head and Neck Surgery still cites smoking is the etiology for 95 percent of patients with vocal cord cancer.

According to the study, tobacco-induced vocal cord cancer takes years/decades to develop. However, HPV presence speeds up the development of vocal cord cancer. The young adults who do smoke haven't been using tobacco long enough for the disease to develop.

Data from the study includes (1) Throat cancer was not encountered in patients 30 years or younger between 1990 and 2004; (2) 11 cases were identified between 2004 and 2018; of those eight had never smoked; and three of those 11 had less than a three-year smoking history (not long enough for the disease to develop); and (3) 10 of the 11 patients tested positive for HR-HPV.

Glucose meters: current regulatory guidance for manufacturers and providers

FDA guidance documents and implications for use under CLIA '88

By Jeffrey A. DuBois, PhD, BCLD/CC (ABB), FAACC

Therapeutic management of blood glucose in patients with diabetes in the home or in the hospital involves the use of glucose meters for the rapid assessment of whole blood glucose. On Oct. 11, 2016, the U.S. Food and Drug Administration (FDA) published guidance documents for glucose meters.[1,2] These guidance documents are for manufacturers, not for providers. The Centers for Medicare and Medicaid Services (CMS) and its designees provide accreditation (certification) for and oversight of provider compliance under the Clinical Laboratory Improvement Amendments (CLIA) of 1988.[3] This is an important distinction for all stakeholders involved in the management of dysglycemia in hospitalized patients, many of who are on intensive insulin therapy to achieve safe and effective glycemic control.

The FDA guidance documents make a clear distinction between devices that are designed, cleared, and classified for self-monitoring of blood glucose in the home and devices that are designed, cleared, and classified for blood glucose monitoring for prescription point-of-care (POC) use. It took six years for the FDA to publish these guidance documents for manufacturers. The initial process involved an open forum on March 16 and 17, 2010, followed by publication of draft guidance documents in January of 2014, which were circulated for public comment and finalized in October of 2016.[1,2] A subsequent FDA advisory panel meeting held on March 30, 2018, addressed the use of capillary whole blood testing with a glucose meter in vulnerable patient populations in acute care facilities.[4] The trigger for the FDA's actions was the compilation of adverse events including numerous deaths in its MAUDE (Manufacturer and User Facility Device Experience) database.[5] These events occurred when self-monitoring blood glucose test systems (SMBG) for over-the-counter (OTC) use migrated into the hospital. During the six years when the FDA was developing new guidance for manufacturers, there was great debate about the performance criteria for glucose meters. Unfortunately, criteria were established by the International Organization for Standardization (ISO), Clinical and Laboratory Standards Institute (CLSI), FDA, and other standards organizations without sufficient evidence about device performance in all patient care settings with all specimen types by CLIA-waived operators.

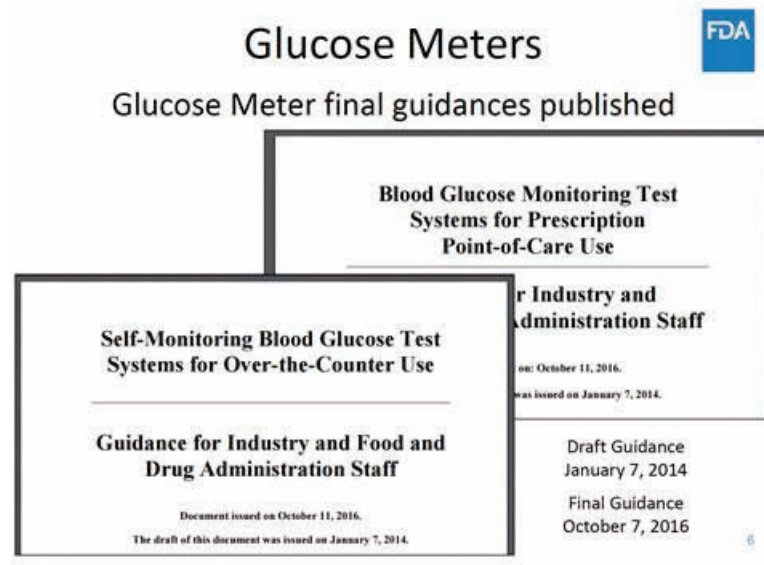

Figure 1. FDA Glucose Meter Guidance Documents

The FDA's publication of two separate guidance documents clearly separates devices into two classes:
1. "Self-Monitoring Blood Glucose Test Systems (SMBG) for Over the Counter (OTC) Use" and
2. "Blood Glucose Monitoring Test Systems (BGMS) for Prescription Point-of-Care (POC) Use" **(Figures 1, 2, and 3)**. To date, there is only one device that is cleared and classified by the FDA as a Blood Glucose Monitoring System (BGMS) for Prescription Point-of-Care (POC) Use **(Figure 4)**.[6,7]

A series of articles were published after this device was cleared by the FDA on Sept. 24, 2016, k132121.[8-10] Other articles[11-13] called for a moratorium on the off-label use of

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LEARNING OBJECTIVES

Upon completion of this article, the reader will be able to:

1. Recall which regulatory agencies are directly involved in the compliance of glucose monitors.
2. Discuss the sequence of events and process for the FDA to provide action and insight on the compliance of glucose monitors in healthcare institutions.
3. Discuss the process for approval for the use of off-label glucose meters in healthcare institutions.
4. Describe the liabilities of the use of off-label glucose meters that healthcare institutions may be subject to.

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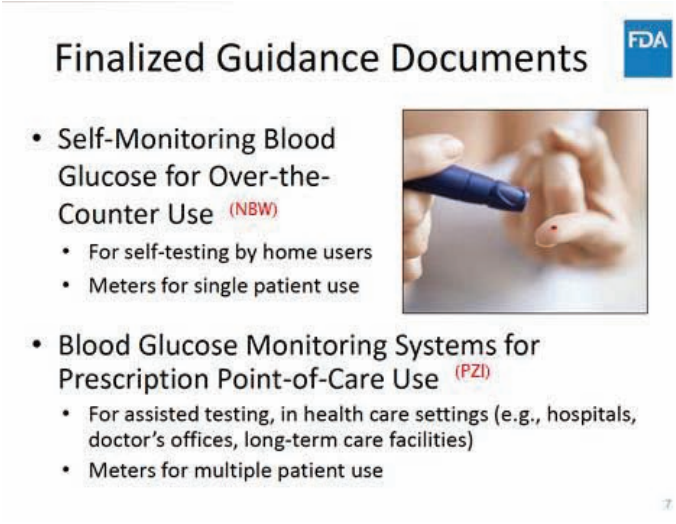

Figure 2. FDA Glucose Meter Guidance Documents

glucose meters following sentinel events in at least two New York State hospitals in early 2014, which required greater scrutiny of the use of these devices in hospitals. As with the performance criteria, much of the information presented in these articles was not evidence based. The concern was that the cleared device did not include the use of capillary whole blood testing in critically ill (vulnerable) patient populations within all healthcare settings. It was thought that this regulatory limitation would compromise diabetes research in these patient care settings.

Subsequently, and after the FDA's Advisory Panel[4] on capillary whole blood, the same device was cleared (k181043) for use by CLIA-waived operators with all patients in all healthcare settings with all specimen types. The device was then classified by the FDA as the only "Prescription Use Blood Glucose Meter For Near Patient Testing" (Product Code PZI).[6,7]

The FDA had established a clear pathway for clearance of devices based on the evidence submitted by this manufacturer over several significant submissions drawing from very large prospective and retrospective (Real World Evidence) datasets, with a combined N=>20,000 paired glucose measurements comparing arterial, capillary, and venous whole blood to central laboratory traceable plasma glucose results. These clearances and the new classification have profound implications for use by providers under CLIA '88.

Use of other devices classified as OTC SMBG (Product Code NBW) based on the FDA guidance is considered off label in hospitals[14] because these devices have not been evaluated for use in these facilities and, specifically, in vulnerable populations such as critically ill patients.

Off-label use under CLIA '88 requires providers to restrict the use of these devices to CLIA-waived operators. This has significant operational considerations within hospitals as to who can perform testing in vulnerable patients including critically ill. When a provider chooses to use a glucose meter off label, the hospital and laboratories must possess a CLIA Certificate of Compliance (CoC) or Certificate of Accreditation (CoA), establish the performance specifications (i.e. accuracy, precision, analytical sensitivity, specificity including interfering substances) and other performance characteristics for use in their patient populations, and meet the additional CLIA regulatory requirements for high-complexity testing as well as any applicable state regulations. Compliance with these rules, however, does not eliminate the *off-label use* of a glucose meter. In addition to patient safety concerns, the *off-label use* of a glucose meter in critically ill patients raises regulatory and legal concerns that may have important implications for both providers and patients.

Consequences under CLIA

Because the conditions for CLIA-waived status (that a test be simple and have a low risk of erroneous results) have only been demonstrated for the test when used according to its labeling:

1. Glucose meters lose their status as CLIA-waived tests when used off label and are considered high complexity tests.
2. If a facility wishes to use a BGMS off label (e.g., in a critically ill patient population when a manufacturers' instructions contain a limitation on critically ill patients), laboratories with a [CLIA waiver] may:
   a. Obtain a CoC or CoA
   b. Establish performance specifications [(i.e. accuracy, precision, analytical sensitivity, analytical specificity including interfering substances, reportable range of test results, reference intervals, and any other performance characteristic required for test performance) for use in their patient population]; and
   c. Meet the additional CLIA regulatory requirements for high-complexity testing and any applicable State regulations.
3. A laboratory/hospital performing high complexity testing that doesn't meet the requirements is subject to a notice of deficiency.

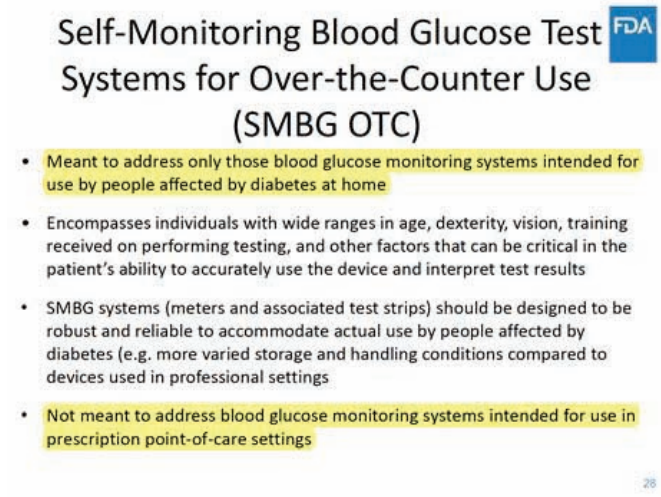

Figure 3. Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use

a. This requires submitting a corrective action plan to CMS or its designee, the College of American Pathologists (CAP).

b. CMS can suspend or revoke a Certificate of Waiver (CoW).

c. CMS can cancel a provider's approval for Medicare reimbursement for failure to comply with the corrective action plan in a timely manner.

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Because *only* a BGMS has been cleared and classified by the FDA for use in vulnerable patient populations, the *off-label use* of other glucose meters with critically ill patients could also present legal risk for providers.

Legal consequences include but are not limited to:

Liability for patient negligence

1. Tort liability for negligence could occur if facility physicians, nurses, staff, or laboratories use a glucose meter off label with a critically ill patient and an inaccurate reading results in patient injury.
2. *Off-label use* of a glucose meter could be used as evidence that providers breached the standard of care, particularly in light of safety communications on this topic issued by the FDA, CMS, and other agencies.
3. The doctrine of informed consent requires that providers disclose the nature of a proposed procedure and its benefits and risks, as well as any feasible alternatives.

New Search | Back To Search Results

Device Classification Name	Prescription Use Blood Glucose Meter For Near-Patient Testing
510(K) Number	K181043
Device Name	StatStrip Glucose Hospital Meter System
Applicant	Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454
Applicant Contact	John Mchale
Correspondent	Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454
Correspondent Contact	John Mchale
Regulation Number	862.1345
Classification Product Code	PZI
Date Received	04/19/2018
Decision Date	07/12/2018
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Clinical Chemistry
510k Review Panel	Clinical Chemistry
FDA Review	Decision Summary
Type	Dual Track
Reviewed By Third Party	No
Combination Product	No

Figure 4. Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use

a. If a provider uses a glucose meter off label and does not inform a patient of the known risks of an inaccurate glucose reading, there is a risk that the patient's consent does not meet the informed consent standard.

b. Under the theory of *respondeat superior* or vicarious liability, the medical facility could be liable for these and other actions of its physicians, nurses, staff, or laboratories with respect to the off- label use of glucose meter in critically ill patients.

Liability for hospital corporate negligence

1. In some states, medical facilities could also be directly liable for a patient's injuries, independent of the actions of its providers.
2. Under the corporate liability doctrine, hospitals have a duty to oversee the practice of medicine within its walls.
3. The fact that the majority of U.S. hospitals choose FDA-cleared devices for testing in their critically ill patients is one that courts could consider when assessing whether a hospital using a glucose meter off label has satisfied a reasonable standard of care for its patient

Liability under CLIA '88 and compliance under:

1. CLIA waiver:
   a. Conditions for CLIA-waived status
   b. Glucose meter loses its status as CLIA-waived test if used off label
2. CMS's guidance (risk to Medicare reimbursement [loss])
   a. High complexity testing not properly performed under CLIA '88
3. State guidance, regulations, non-compliance actions impacting accreditation and possibly reimbursement. Agencies include but are not limited to:
   a. New York and Washington State health departments
   b. The Joint Commission
   c. CAP
   d. ECRI

Conclusion

In summary, the off-label use of a glucose meter or any medical device can result in charges against providers and hospitals for negligence and medical malpractice as a result of not following the doctrine of informed consent or maintaining the standard of care, which can result in medical board investigations. Non-compliance with CMS can possibly affect accreditation (license) and reimbursement including liability for false claims.

The StatStrip Glucose Hospital Meter System is a professional BGMS for prescription POC use that is cleared and classified (Produce Code PZI) for use in all patient care settings with all specimen types by CLIA-waived staff.

As of today, based on device limitations and NBW classification, the use of all other glucose meters in acute care facilities is considered off label by the FDA. The patient safety, legal, and regulatory consequences for *off-label* use are significant and should be avoided. It is important for institutions to consult their risk management and legal offices regarding off-label use of a glucose meter.

Please visit mlo-online.com for references.

Jeffery A. DuBois, PhD, BCLD/CC (ABB), FAACC, serves as Vice President Medical and Scientific Affairs, **Nova Biomedical Corporation.**

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Glucose meters: current regulatory guidance for manufacturers and providers

April 2019 *[This form may be photocopied. It is no longer valid for CEUs after October 31, 2020.)*

TEST QUESTIONS

Circles must be filled in, or test will not be graded. Shade circles like this: ● Not like this: Ⓧ

1. **FDA published guidance documents for glucose meters are intended for use by**
   - a. providers.
   - b. manufacturers.
   - c. patients.
   - d. all of the above

2. **What regulatory body provides accreditation and oversight of provider compliance for glucose meters?**
   - a. CMS
   - b. FDA
   - c. CLIA '88
   - d. The Joint Commission

3. **FDA guidance documents make a clear distinction between device use of glucose meters in the home vs. glucose meters for prescription point of care (POC).**
   - a. True
   - b. False

4. **The FDA's purpose for creating the guidelines were due to adverse events and numerous deaths when**
   - a. self-monitoring blood glucose systems (SMBG) for over-the-counter (OTC) use migrated into the hospital.
   - b. glucose monitors for POC testing use weren't calibrated by the user each day.
   - c. glucose monitors for POC testing were taken home by the patient for personal use.
   - d. none of the above

5. **When the FDA was creating new guidance for manufacturers, what problems were identified with original guidelines about performance criteria?**
   - a. lack of evidence of device performance in all patient care settings
   - b. lack of evidence of device performance with all specimen types
   - c. both a. and b.
   - d. none of the above

6. **Currently there is/are _____ device(s) that is/are cleared and classified by the FDA as a blood glucose monitoring test system (BGMS) for prescription POC use.**
   - a. 0
   - b. 1
   - c. 5
   - d. 10

7. **After the FDA clearance of the only glucose monitoring device, there was growing concern that the device did not include the use of**
   - a. arterial whole blood testing in acute care patients within all healthcare settings.
   - b. capillary whole blood testing in acute care patients within all healthcare settings.
   - c. arterial whole blood testing in critically ill patients within all healthcare settings.
   - d. capillary whole blood testing in critically ill patients within all healthcare settings.

8. **The only FDA cleared glucose monitoring device was not approved for use by CLIA-waived operators.**
   - a. True
   - b. False

9. **An OTC SMBG device used in a hospital setting is considered**
   - a. off-label.
   - b. on-label.
   - c. CLIA un-waived.
   - d. none of the above

10. **Compliance with rules and regulations of an off-label glucose monitor poses regulatory and legal concerns for providers and patients.**
    - a. True
    - b. False

11. **When are glucose monitors considered high complexity testing?**
    - a. When the hospital demonstrates compliance to all regulatory and compliance rules regarding the use of the meter.
    - b. When the hospital uses an FDA-cleared meter.
    - c. When a hospital chooses to use an off-label meter.
    - d. all of the above

12. **When a hospital chooses to use an OTC SMBG, the hospital and labs must**
    - a. meet any applicable state regulations.
    - b. establish performance specifications and other performance characteristics.
    - c. have a CLIA certificate of compliance and meet additional CLIA regulatory requirements for high complexity testing.
    - d. all of the above

13. **Legal consequences can occur with the use of off-label glucose meters and the liability(ies) than can occur is/are**
    - a. patient negligence.
    - b. hospital corporate negligence.
    - c. CLIA '88 compliance.
    - d. all of the above

14. **Tort liability can occur if**
    - a. a facility uses an FDA cleared glucose meter with a critically ill patient that results in patient injury.
    - b. a facility uses an off-label glucose meter with a critically ill patient that results in patient injury.
    - c. a breach of standard of care is identified.
    - d. there is no communication to the patient informing them of their risk.

15. **If informed consent is not provided to patients in regard to off-label use of glucose monitors, liability can occur under the theory of**
    - a. *respondeat inferior.*
    - b. *respondeat superior.*
    - c. *despondeat inferior.*
    - d. *despondeat superior.*

16. **Medical facilities are protected and are not directly liable for a patient's injuries in the use of off-label glucose meters.**
    - a. True
    - b. False

17. **What departments of a healthcare institution should a lab work with in the use of off-label blood glucose monitors?**
    - a. human resources and patient advocate
    - b. risk management and human resources
    - c. risk management and legal
    - d. legal and human resources

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2019 Lab of the Year:
Penn Medicine Lancaster General Health Laboratory

By MLO Staff

2019 FIRST PLACE WINNER

Selecting a Lab of the Year is never an easy task thanks to the outstanding nominations *MLO* receives year after year. And since history tends to repeat itself, 2019 was no different. With much respect and admiration, *MLO* is proud to present the 2019 LOY winner: Penn Medicine Lancaster General Health Laboratory!

Located in Southern Pennsylvania, approximately 70 miles west of Philadelphia, sits Lancaster General Health Laboratory, part of Lancaster General Hospital (LGH). This 533-bed, nonprofit hospital is part of Lancaster General Health/Penn Medicine, a member of the University of Pennsylvania Health System (Penn Medicine). LGH offers a full range of tertiary services. It also includes the Women & Babies Hospital (WBH), a 97-bed specialty hospital and adjoining outpatient center focused on the healthcare needs of women at every stage of life and their newborn babies. LGH is also part of the Ann B. Barshinger Cancer Institute (ABBCI), a state-of-the-art facility offering access to a multispecialty network of professionals.

2018 marked the 125th anniversary of the institution and its service to the Lancaster Community. Designated a Magnet hospital for nursing excellence four consecutive times, LGH has been recognized regionally and nationally for clinical excellence and patient safety. Recognized among *U.S. News & World Report's* Best Hospitals for 2017-18, LGH was also ranked sixth among Pennsylvania hospitals and named Best Regional Hospital.

Lancaster General Health Laboratory serves 75 percent of the county's healthcare market. The lab is accredited by the College of American Pathologists (CAP) Laboratory Accreditation Program, CAP ISO 15189, AABB, and FDA. There are two fixed laboratory sites serving the system with multiple point-of-care testing (POCT) sites serving 16 ambulatory locations. The laboratory system at Lancaster General Health holds 19 CLIA Certificates, including High Complexity, Moderate Complexity, and Waived.

Pathologist case review

The laboratories offer a full range of clinical laboratory and anatomical pathology services including (a) General Laboratory Testing of Individual Lab Tests at LGH and WBH, (b) Pathology and Cytology Services, (c) Microbiology Testing, and (d) Blood Bank & Blood Bank Donor Center.

The laboratory completed a multimillion-dollar expansion in 2014. The original square footage of 28,000 expanded to a 43,000-square-foot laboratory that performs more than two million tests each year. The clinical laboratory renovation was a five-phase project spanning five years.

Customer service

Both inpatient and outpatient providers order tests through the electronic medical record (EMR). Orders are placed directly in the EMR by the physician—eliminating transcription order errors. Inpatient orders are downloaded to the phlebotomy hand-held units. Upon receipt of the test order the phlebotomist scans the patient ID bracelet, confirming the correct patient, and prints the labels for bedside collection. Since the implementation of hand-held scanning devices and printers, the phlebotomy department consistently maintained a low deviation rate for misidentified samples. In 2018, the phlebotomy department reached 356 days without a defect. The phlebotomy department was awarded the Penn System 2018 Quality and Safety Award, Honorable Mention for Positive Patient Identification.

LGH laboratories offer convenience and easy access to outpatient services. There are 15 ambulatory draw sites in Lancaster county and two surrounding counties. Each site offers POCT for Protime/INR, and some sites offer additional POCT based on the services provided on-site, as well as pregnancy and creatinine for diagnostic imaging. The hospital courier department provides services to each ambulatory draw site, as well as Lancaster general physician offices. The samples are delivered to the LGH or WBH laboratories. The ambulatory draw sites use the laboratory information system (LIS)—samples are tracked on transport lists and lab pending lists to ensure specimen safe delivery.

The Off-Site Services department provides patient services for 25 extended care facilities in Lancaster and Lebanon counties with 4,157 skilled care beds overall. Routine and 24/7 STAT phlebotomy are provided. Starting this year, the team will be working with 23 area group homes to bring phlebotomy to their individual residences. This program is designed to help patients who are fearful of phlebotomy procedures and avoid compliance to necessary testing. This volume results in over 115,000 tests annually.

The Lancaster General Blood Bank is self-sufficient in that 90 to 95 percent of products transfused are collected at the Lancaster General Donor Center. The Donor Center supports a fixed site and mobile blood drive operations. Three community blood drives occur each week in the county. The Donor Center collects and processes approximately 10,000 donations per year including platelet pheresis for single donor platelet products.

A hospital transportation service is available to community members for transportation to and from blood drives. Many of the donor population comes from the Amish community and others in the community who want to participate but face transportation barriers.

Productivity

The Microbiology department has implemented the BD (Becton, Dickinson and Company) Laboratory Automation System. In 2013 the LGH laboratory went live with the InoqulA—an automated plating system which brings standardization to specimen plating. The final phase of the automation system was completed in 2017.

Microbiology Technologists logging samples in LIS

Microbiology is the 2018 LGH Patient Safety overall winner for the Most Enhancement to Safe Practice and the 2017 Operational Winner of the Penn Medicine/Lancaster General Health Quality and Safety Award for Microbiology automated system improvements. It was designated as a Cepheid Center of Excellence in 2018 by the company.

The fully automated Core Lab has a front-loading system connected to a line that transports samples to the chemistry, immunology, and urinalysis instruments. Another line for Hematology transports samples through the hematology analyzer/slide stainer and WBC differentials are read on a digital cell reader. Middleware is utilized to monitor and automatically release patient results from the LIS into the EMR based on defined limits.

Pathology utilizes a bar coding system, Vantage, for patient identification for sample grossing and processing in histology, reducing labeling errors by 94 percent.

In the Blood Bank, 6-/7-day platelet product expiration extension with bacterial detection testing was implemented which resulted in discarding 39 percent less single donor platelets. This resulted in less recruiting/collection of donors and the conservation of the donor pool.

Teamwork

LGH's laboratory is focused on the continuum of care. Working closely with physician practices, they realized how the lab could assist in helping their patients meet screening requirements for colorectal cancer. An in-home testing product was selected by the Medical Director based upon sensitivity and specificity as well as ease of use for

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qualified patients. The laboratory tracks trends in physician orders, patient returns, and positive/negative results—reporting this information on a weekly basis. Receiving timely information allows physicians to provide early detection and treatment.

Microbiology Technologists performing digital plate reading

The Outreach Manager and Microbiology Manager are members on the Infection Control and Antibiotic Stewardship committees at each of the nursing homes serviced by Lancaster General Health Laboratory to offer expert guidance. One of the tools that has come about through this partnership is an antibiogram based on the patient population.

Lancaster General Health's partnership with a new Behavioral Health Hospital which opened in 2018 allowed them to provide mobile laboratory and diagnosis services to a group of formerly underserved patient population in the community.

LGH has implemented a huddle process across the organization. Each department has daily huddles and huddle boards that are used to evaluate work processes to generate ideas for improvement.

Education and training

Mandatory annual continuing education programs are required for all laboratory staff. In addition, every employee is required to complete additional elective continuing education programs of their choosing. The content of the elective programs is reviewed with their immediate supervisor for approval. The department manager is responsible to prepare a yearly listing of educational activities available to employees, the Medical Director is responsible for approving the listing.

Recently the entire laboratory implemented an electronic document control system. All laboratory departments transitioned from a paper system to electronic systems in MediaLab.

The Electronic Document Control System for lab-wide policies and procedures ensures the current version of policies and procedures are available for staff at all laboratory sites. Users access policies and procedures electronically at the bench by desk-top computers and iPads. There is electronic access to the current version of policies and procedures for all laboratory departments. Each Ambulatory Lab has a corresponding site in MediaLab where staff can access site-specific policies and procedures. Staff members receive mail notification when a new document or major revisions are applicable to their jobs and automatically notifies supervisors if employees haven't signed-off on time.

There's also a process in MediaLab for periodic staff reviews of policies and procedures with documentation. And most importantly, it eliminated paper copies of procedure manuals! Today, the two fixed laboratories and Ambulatory Draw Sites are paperless.

Strategic outlook

Last summer, LGH joined their Penn Medicine colleagues in adopting the following Penn Medicine Experience Standards:

- Be compassionate: I serve with my head and heart.
- Be Present: I show up and remain engaged.
- Be Empowered: I drive results with intention.
- Be Collaborative: I partner with unwavering support.
- Be Accountable: I commit to every single moment.

LGH also continued deployment of the Lean Management System to align with the following senior level goals:

- Development of Huddle Board Quality Metrics.
- Gemba (a Japanese term meaning "the actual place") Walks to identify and eliminate waste.
- Engage staff regarding problem solving in their area.
- Use of Process Standard Work.
- Corrective Actions through Plan-Do-Check-Act cycles.

Lab inspections

In 2018 the LGH lab implemented MediaLab Electronic Accreditation System, InspectionProof. The software allows for inspection documentation in one system. Documentation for checklist items are completed by entering text responses, uploading supporting files, and linking to policies and procedures. Compliance to CAP requirement is measured by the system.

Additionally, the laboratory has an internal audit team comprised of staff technologists. All members participate in ISO 15189 educational courses on internal auditing. The audit team developed the program's policies, procedures, and training process. The first audit cycle started in 2014 after the CAP on-site inspection. A trained lab auditor audits each lab department once a year. The internal audit team helps each department to stay inspection ready.

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Consequences of FDA Changes to Critically Ill Bedside Glucose Testing Regulations

Clinical Consequences

Venous, Arterial, and Now Capillary Specimens Are All FDA Cleared for Critical Care Patient Testing – Are All Specimen Types Analytically and Clinically Equivalent?

The choice of specimen type is an important consideration, particularly for critically ill patients. This presentation will discuss the analytical performance differences between specimen types and their clinical significance. The data is based on the results of an FDA submission comparison study of 16,778 paired patient test results.

Learning objectives:

- Analytical performance differences
- Clinical significance of these differences
- Suggested best practices for testing

Presenter:
Evan Ntrivalas, MD, PhD
MASA Director, North America
Nova Biomedical

Clinical Impact of Glucose Meter Accuracy in Critically Ill Patients

Critically ill patients often present with medications and physiological factors that can interfere with glucose meter measurement. Interferences can cause glucose meter errors, insulin misdosing, and adverse events. This presentation will discuss the clinical impact of a glucose meter that measures and corrects for interferences.

Learning objectives:

- Analytical and clinical impact of meter interferences
- Improved outcomes achieved with a glucose meter that measures and corrects for interferences

Presenters:
Martha Lyon, PhD*
Clinical Biochemist/Clinical Associate
Saskatoon, Saskatchewan, Canada
or
William A. Clarke, PhD**
Director, Clinical Toxicology, Professor of Pathology
The Johns Hopkins Hospital

Regulatory/Legal Consequences

Regulatory Requirements for Off-Label Testing and Consequences of Non-Compliance

Nova's StatStrip glucose meter is FDA cleared and CLIA waived for use with all patients including critically ill. Use of all other meters with any critically ill patient population is considered off label by the FDA and CMS. This presentation will discuss the history and rationale for recent FDA changes to critically ill bedside testing and the regulatory and legal consequences of off-label testing for caregivers and hospitals.

Learning objectives:

- FDA changes to bedside glucose testing, 2010-2019
- When bedside glucose testing is off label
- FDA requirements for off-label bedside glucose testing
- Patient risks if performing off-label testing in critically ill patients
- Caregiver and hospital liability when performing off-label glucose testing
- CLIA risks when performing off-label glucose testing

Presenter:
Natalia Mazina
Healthcare and pharmacy attorney specializing in FDA medical device and pharmaceutical compliance

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First runner-up:
UMC Lubbock Clinical Laboratory

University Medical Center (UMC), formed in 1996 to meet the needs of the community, is a non-profit, 500-bed facility located in Lubbock, Texas. Over 125 providers represent all primary care specialists and locations throughout West Texas. UMC is the only Level 1 Trauma Center in the area and is the only Burn Center in the region. The children's unit is part of the Children's Miracle Network and includes both pediatric and neonatal intensive care units. It also serves as the teaching hospital for the Texas Tech University Health Science Center (TTUHSC).

UMC was named one the best companies to work for in Texas six of the past seven years with a featured article in *Texas Monthly*. *Most Wired: Health Care's Most Wired* acknowledged UMC as having a higher level of technology adoption, geared toward improved patient care and safety.

UMC also received Magnet Designation and joined the top seven percent of hospitals in the nation by earning Magnet Recognition from the American Nurses Credentialing Center—one of the highest achievements a hospital can attain.

In 2018, the UMC Clinical Laboratory had a complete transformation including a new laboratory director, assistant director, supervisors, and a total renovation of the clinical laboratory. Employee satisfaction rose to 99 percent overall vs. the previous year's 73 percent.

Customer service

UMC Clinical Laboratory provides an online portal for external customers to connect with physicians and their medical records. The system facilitates communication with the primary healthcare provider and allows access to crucial documents such as medications, immunizations, medical history, and test results. Physicians, nurses, and employees have specialized portal access.

UMC has multiple clinics surrounding Lubbock which makes it convenient and efficient for patients to receive treatment and phlebotomy services. This number has increased steadily to over 48,000 annual phlebotomy collections for these outpatient clinics.

Customer service at UMC also includes its employees. Their Wellness Program addresses the well-being of staff by providing participation challenges. Completion of these challenges earns points. Quarterly and annual prizes are awarded based on point totals.

Productivity

The Chemistry department purchased two Roche COBAS 8000 analyzers to meet the needs of increased laboratory testing (1.3 million tests per year). The Hematology department also purchased a new analyzer and the instrumentation was attached to an automated line. The whole laboratory was renovated to be Lean. Hematology lead the way into innovation by installing the Sysmex XN-9100 and the Sysmex SP-50 Slide Makes/Stainer. The reduction in manual differential percentage from the previous analyzer decreased from 27 to 11 percent in the first three months. New advanced hematology parameters were introduced to assist providers in diagnosis, treatment, and maintenance of several patient conditions to include immature platelet fractions, reticulocyte hemoglobin, and immature granulocytes. The auto-validation rate for the Sysmex was 70 to 75 percent vs. 20 percent for the previous analyzer.

Gary Escoto, MLS(ASCP), JoseLuis Sanchez, MS, MLS(ASCP), and Aubrey Lacirda, MT(AMT) observing Total Lab Automation ribbon cutting presentation

Implementation of an Individualized Quality Control Plan (IQCP) program for thromboelastogram (TEG) testing projected savings of $87k per year. In addition, Transfusion Services installed a new Neo analyzer which expanded testing to include phenotyping and batch testing for in and out patients to assist with prioritizing STAT testing as to not delay patient care.

The laboratory also participated in UMCs Annual Waste Walk to promote efficiency which yielded $5.3

continued on page 25

- [ ] Has your current lab director signed all documents?
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Second runner-up:
LifeSouth Community Blood Centers

LifeSouth Community Blood Centers was established in 1974 as a nonprofit organization in Gainesville, Florida. Today they have more than 900 employees (74 FTEs across their laboratories), 30 locations, and 54 bloodmobiles, they partner with more than 100 hospitals in Florida, Alabama, and Georgia.

LifeSouth has two Immunohematology Reference Labs (IRLs) based in Gainesville, FL and Atlanta, GA. Their Quality Control Labs (QCLs) provide analytical testing to ensure the safety, purity, and potency of their blood components and cord blood products. Their Cord Blood Bank (CBB) is one of seven public CBBs licensed by the FDA and produces the biological drug product CORDCYTE. The CBB collects umbilical cord blood at 11 of their partner hospitals. Transfusion Services are provided for select area hospitals.

Customer service

LifeSouth achieves its mission of excellence by adhering STARS, which stands for **S**afety, **T**eamwork, **A** Difference, **R**eputation, and **S**tewardship.

The IRLs contribute to the American Rare Donor Program (ARDP) and participate in AABB's National Blood Exchange (NBE).

Demonstration of proper pipetting technique for molecular testing

In addition to highly skilled and certified technologists and Specialists in Blood Banking (SBBs), they have a Quality Assurance (QA) department which conducts regular reviews and audits. Each lab has a designated QA representative.

LifeSouth has an in-house Technical Communications department which specializes in technical writing and instructional design, as well as a Laboratory Resource Management team in Gainesville dedicated to internal/external blood component logistics and customer service.

Their Medical Directors are board certified in Blood Banking and Transfusion Medicine. The medical team provides a 24/7/365 consultation MD Hotline Service.

Productivity

The lab's certified technologists and specialists performed nearly 85,000 tests in 2018. Tests performed on blood components include hematocrits and platelet counts on a Sysmex XE-2100D, residual WBCs using BD's FACSCantoII flow cytometers, HLA antibody detection using the Luminex 200 and 3D, and microbial detection testing using Verax Platelet PGD Test.

Tests performed for cord blood products include complete blood counts on their two XE-2100D hematology analyzers; CD34/CD45 enumeration and viability, nRBC, and total WBC viability by flow cytometry; colony forming units (CFUs) using STEMVision; sterility testing using bioMérieux's BACT/ALERT; and hemoglobinopathy testing using capillary electrophoresis.

Their CBB adopted both an automated processing platform (Sepax – GE Healthcare) and an automated cryopreservation platform (BioSafe – Thermogenesis) which robotically moves the unit after a controlled rate of freezing. They use a closed processing kit by GE Healthcare and sterile docking devices to reduce bioburden risk.

LifeSouth has a unique in-house software development team. To better meet their customers' needs, the IRLs final report includes donor compatibility percentages based on patient antibodies present, supplementary information to assist with the interpretation of results, transfusion recommendations, and applicable references to articles.

Education and training

Each lab has designated Area Safety Coordinators (ASCs) who monitor safety practices and conduct emergency drills. Together with the laboratory's QA representative, nonconformities are monitored for trends and protocols for Corrective Action Preventive Action (CAPA). Lab staff participates in root cause analysis (RCA) and follow a systemic plan to avoid recurrence.

A dedicated Laboratory Training Coordinator manages distribution and completion of training and competency assignments.

UMC continued from page 22

LifeSouth has one of only two Florida donor center-based Medical Technology Training Programs for Blood Bank and Immunohematology (MTBB). Since its inception, 30 MTs have graduated. Up to four qualified students are hired as LifeSouth employees. Trainees receive full-time benefits and pay, including all books, training materials, license, and exam fees. In exchange, the new med techs make a two-year work commitment. Since its beginning, 90 percent of participants worked beyond their two-year commitment, and 57 percent are still employed.

Teamwork

LifeSouth's laboratories overcome challenges with the help of management and their Medical Directors. Their QA department meets monthly with staff to monitor and discuss deviations, proficiency testing, validations, audits, procedure change requests, and staff training.

LifeSouth provides opportunities for staff to recognize the efforts of their coworkers and managers through a system of "STARS points." Employees are awarded points on a quarterly basis. Staff members nominate others online, with an explanation of which of the company values a fellow employee exemplifies. Points are then redeemed for prizes.

Strategic outlook

In addition to being a Center of Excellence in the Southeast, the CBB objectives include doubling the size of their hospital network; isolating and expanding mesenchymal stem cells (MSC) that are capable of differentiating down adipogenic, osteogenic, and chondrogenic lineages; adding an additional Class 6 clean room for cord blood processing; and participating in clinical research projects.

Their Laboratory Resource Management team is in the process of implementing a Centralized Order Management (COM) model. Trained staff will be available 24/7 to receive and coordinate orders which allows for the customer to have a single point of contact.

LifeSouth continues to expand. An IRL was brought online in Atlanta and they plan to open another IRL in Jacksonville. They are also working with the National Blood Collaborative to open a donor testing lab in Atlanta, as well as becoming accredited to perform HLA home testing.

More than 70,000 LifeSouth blood donors have been genotyped since 2007 to identify compatible donors for patients requiring red blood cells with special antigen phenotypes for transfusion. As a result, they're able to support the large sickle cell population and are building a dedicated lab space for molecular testing.

Lab inspections

LifeSouth is a member of and accredited by the AABB. The AABB inspection for Blood Bank and Transfusion Services in 2017 resulted in zero non-conformances for the laboratories, and the most recent FDA inspection reported no 483 observations. The CBB is one of the first cord blood banks to become accredited by the Foundation for Accreditation for Cellular Therapy (FACT). The CBB is also a member bank of the National Marrow Donor Program (NMDP). It has been inspected by the FDA, NMDP, HRSA, and FACT. The QCLs have been inspected by the AABB, FDA, and FACT under the CBB with no deficiencies.

million dollars in savings which is allocated to employees for their Sharing Success Bonus.

Teamwork

The 2018 Employee Satisfaction Survey was nationally ranked at the 99th percentile. A "Behind the Badge Campaign" was implemented by UMC and is a standard that addresses the need to value the person behind the badge. This is a recognition, respect, and replenish campaign to assist each employee to take care of themselves.

The teamwork at UMC clinical laboratory goes far beyond the clinical setting. Staff volunteers every third Sunday of the month to provide meals to those in need.

Education and training

Education and training within the UMC Clinical Laboratory focuses on enabling employees to engage and grow within their profession, organization, and community. The implementation of a "Career Ladder" bolsters learning and participation via individual projects, maintaining CEU's by purchasing membership through MediaLab for all employees, organizational participation, and community service. Phlebotomists, processers, and technologists can also benefit from participation by receiving a monetary reward for completion of the criteria and has reward levels of $500, $1,000, $1,500, and $2,000. The clinical lab's affiliation with TTUHSC allows CLS students to complete rotations within each department; many of who are hired as employees. Lab staff is encouraged to train on- and off- site with every analyzer in each department. Cross training is also encouraged for employees who want to learn the processes of other departments and serves as a pathway for advancement. Leadership encourages staff members to apply and continue their education with CAP to become certified laboratory inspectors. Tuition reimbursement is also offered.

Strategic outlook

The clinical laboratory implements pillars for a strategic plan. The pillars serve as a pathway toward success and align with the culture set forth with UMC hospital. Each pillar focuses on several important actions along with the vision and mission for each department. For example, the service pillar addresses the entire patient experience from stem to stern with the goal to differentiate the clinical lab as the market leader in patient satisfaction.

Lab inspections

In 2018 the clinical laboratory had a successful DMV, FDA, and AABB inspection. An upcoming 2019 CAP inspection has everyone pulling together to ensure compliance and seek out issues needing resolution. UMC's laboratory had several citations in 2017. Some were corrected on-site, and others had corrective actions performed to ensure compliance. Supervisors delegated additional duties to the technologists to ensure full compliance with CAP. Continuous process improvement is a job that everyone in the laboratory performs.

Using analytics to manage QA and reduce laboratory errors

By Vanessa Hawrylak, MS, MT(ASCP), Thomas Joseph, MBA, MT(ASCP), Tim Bickley, MT(ASCP), MBA, CPHIMS, and Kristina Ziaugra

Today, many laboratories are still measuring their data manually, a time-consuming process subject to human error. Laboratory managers often struggle to obtain timely metrics, as laboratory information systems (LIS) provide only limited management reports, and often the metrics received are a month old and thus of limited value in improving quality and reducing errors. As a result, laboratories are increasingly turning to laboratory analytics/business intelligence as a solution to these challenges for their data mining needs. A laboratory analytics system, however, processes a wealth of laboratory data in seconds, not only ensuring that laboratory management has more time to focus on other tasks, but also providing the means for managers and supervisors to monitor and maintain higher standards of quality. Laboratory analytics are proving to be a beneficial tool in ensuring that large amounts of data can be analyzed and presented in meaningful reports that easily identify opportunities to catch and correct laboratory errors such as specimen defects, shifts in analyzer results, inappropriate utilization of laboratory tests, and can also be used as evidence of compliance (EOC) to accrediting laboratory compliance agencies.

Specimen defects and reference range changes

Laboratory analytics/business intelligence tools can assist in identifying specimen defects, which is necessary to determine areas of improvement. Important specimen information can be captured, such as how many specimens are ranked Quantity Not Sufficient (QNS), or the number of hemolyzed specimens, with detailed information such as who collected the specimen and where the specimen was collected. A hemolyzed or QNS specimen requires re-sticking a patient and can create a delay in result reporting.

With an effective laboratory analytics system in place, managers can easily view all specimens for hemolysis and QNS rates and take necessary corrective action. The laboratory business intelligence/analytics system provides insight into where a hemolyzed specimen came from, what clinic, which ward, and even the nurse or phlebotomist who drew the specimen. By performing hemolysis and QNS audits to identify patient locations and collection, staff members with the highest number and proportion of occurrences can be identified. Laboratory management can then act to identify which staff members require retraining to improve quality. While it may not be possible to retrain everyone for all quality problems, it is possible to identify where most quality assurance (QA) issues originate, providing management with the insight to focus retraining for the greatest effect.

Defective test results can pose significant financial implications to the health system when lab tests are misinterpreted and misused. An analytics system can generate a comparison of test results that allows laboratory management to see definitive analytic results to quickly answer questions about instrument performance over time. With data available daily, management can ensure that a performance problem never goes undetected and that quality managers and lab directors are kept aware of the source of laboratory problems.

Inappropriate test utilization

The consequences of unnecessary testing for patient care can include iatrogenic anemia, time spent on insignificant abnormal results, incorrect diagnoses, and longer length of stay. Various strategies can be employed to reduce overutilization of testing, including requisition redesign, hard and soft stops in the computerized physician order entry (CPOE), test formularies, education, and audits. No one strategy is sufficient, however, and an auditing capability plays a critical role. With the data from a real-time analytics system, laboratory managers will know the most important areas of unnecessary testing so rules can be developed for the electronic health record (EHR), providing soft stop guidance to physicians. A real-time analytics system also identifies common categories of unnecessary testing. These common categories range from screening/reflexing/normalcy, such as ordering an FT4 when the TSH is normal, to redundant testing such as troponin and CKMBs ordered together, to excessive frequency of repeat testing (e.g., HbA1c should not be ordered more than once every 21 days). From this, laboratory management can identify benchmarks based on tests per inpatient admission, length of stay, and length of stay vs. tests per admission. Using this data and benchmarks, laboratories can develop strategies, and measures can be taken to limit obsolete tests, limit esoteric tests, and minimize bundles of tests.

Shifts and trends in analyzer results

A laboratory analytics system can assist in reducing lab errors by providing a means to monitor quality control (QC) and assist in identifying shifts and trends in analyzer results. For example, analysis using either coefficient of variation ratio (CVR) and standard deviation index (SDI) or a standard analytical null hypothesis theory provides two different approaches to quickly determine if any instruments are reporting

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differently than others. An analytics system's system also supports labs implementing the CMS/CLIA prescribed Individualized Quality Control Plan (IQCP) based on CLSI EP23 guidelines. Best practices are identified using sigma ratings of instruments for each analyte to determine the appropriate number and frequency of QC samples to run. With real-time assessment of instrument performance, labs can know immediately if an instrument problem occurs and if their instruments are not reporting in line with other analyzers. The ability to identify reporting differences between instruments over time allows the laboratory to monitor the quality of their lab results through the analytic testing phase. Access to this type of analytics ensures that QC practices are properly implemented so laboratories can avoid repeat testing, unnecessary follow-up testing, and misdiagnoses. This is also useful for comparing lot changes, new methods, or comparisons every six months as required by accrediting lab compliance agencies.

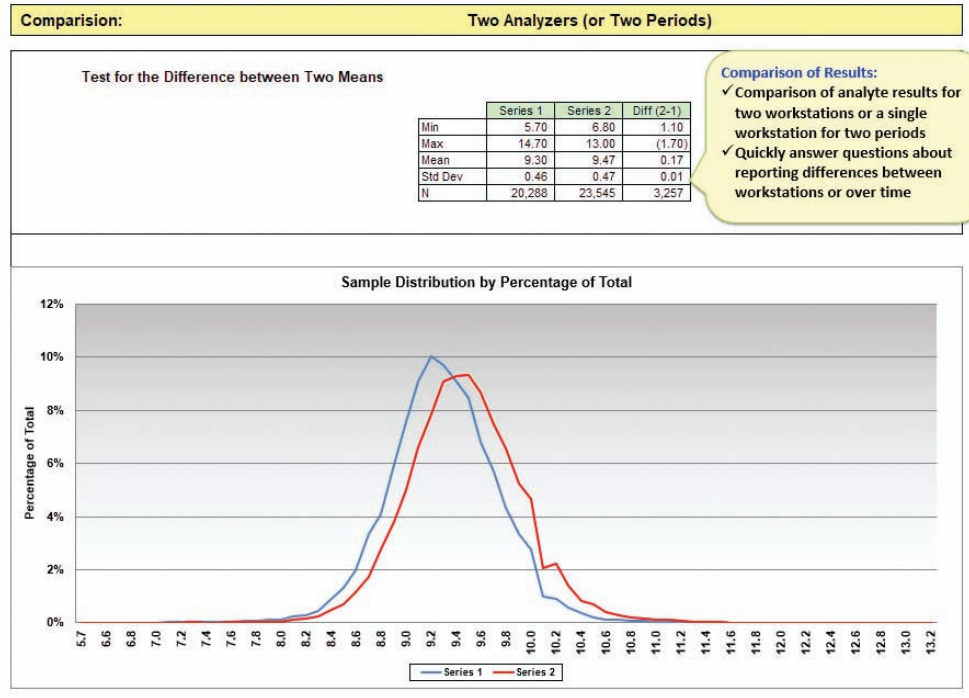

Figure 1-Identifying errors concerning reporting differences between instruments (workstations) of the same methods over time allows the laboratory to monitor the quality of its lab results. A comparison of analyte results for two workstations or a single workstation for two periods as seen on Figure 1 allows laboratory management to quickly answer questions about reporting differences between workstations over time. This is useful for comparing lot changes, new methods, or comparisons every six months as required by accrediting lab agencies.

Demonstrating evidence of compliance

Detailed laboratory analytic reporting can also be used as EOC to demonstrate adherence with requirements related to quality management by agencies such as CAP. Not only can the reporting from a laboratory analytics system offer a clear, at-a-glance guide to see what analytic reports support specific checklist requirements, but it can also be used to set benchmarks for specific quality metrics involved in quality management. Some examples include:

- Demonstrating specimen defects by comments such as cancellation reasons, result corrections, and specimen dispositions
- Analyzing specimen abnormal flags (critical values, diluted samples, delta checks) on a daily, weekly, or monthly basis
- Identifying instrument to instrument correlations for analyzers with the same test and method
- Verifying that analyzer reports automated by the LIS applied rules that are compliant

Having access to these in-depth quality reports helps to identify and reduce laboratory errors, manage QA, and ensures that laboratory management teams have adequate documentation and supporting information to demonstrate adherence to accrediting laboratory compliance agencies.

Conclusion

With data readily available, laboratory management can view all their test results and not only identify errors but also retrace their root cause, delivering actionable information to monitor and improve QA processes. Subsequently, this improves the quality of laboratory measurements and enables management to verify that all processes are operating to set standards of performance. Daily management with a laboratory analytics system and an engaged leadership team are essential components in monitoring QA and reducing lab errors. When laboratory data is managed daily, dramatic improvements can be made and errors can be eliminated, resulting in improved specimen quality, utilization, instrument/analyte performance, and patient safety.

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Complement testing—past, present, and future

By Laura Oversmith, BSB

For more than 60 years, clinicians have been assessing complement components to measure deficiencies or abnormalities. It is very important to understand the causes of low or absent complement so that appropriate treatment and care may be given. Complement analysis is also used to define disease severity and response to therapy, making it very useful for patient management.

History of complement

How did "complement" get its name? In the late 19th century, the focus of scientific research was on the human body's defense against microbial infection. Scientists tried to ascertain what part of the blood destroyed invading bacteria. The Theory of Metchnikoff proposed that phagocytes ingested and destroyed invading bacteria and therefore provided the basis of innate cellular immunity. Further, Paul Ehrlich provided the theoretical basis for immunology; he surmised that between the antigen and the antibody there was an additional immune molecule called a "complement."[1] Paul Ehrlich and Ilya Ilich Metchnikoff were both awarded the Nobel Prize for Medicine in 1908.

What is the Complement System?

The Complement System is composed of 30 blood proteins that are numbered as complement proteins: C1 to C9 with some appended with additional letter designation, e.g. C3c, C5a, C5b. These proteins function in an ordered fashion to defend against infection, coat microbes, send chemical signals, and create the membrane attack complex (MAC), which results in lysis of the pathogen.

Most complement proteins are produced in the liver. There are three key biochemical pathways that activate the complement system: Classical Pathway, Alternative Pathway, and Lectin Pathway. All of these pathways have distinct recognition molecules or activation triggers.

Three reasons to measure complement

There are a several reasons why complement component measurements are requested to assess deficiencies or abnormalities in the complement system.

First, clinicians may be looking to see whether a patient has an absence of a specific protein, or a protein that is non-functional. This is generally a primary immunodeficiency. Second, the clinician could be looking for consumption, where an over-activation of complement pathways results in low levels of complement proteins. Third, a relatively new area for complement measurement is monitoring patients who are on immunosuppressive drugs.

Clinical presentations vary

The clinical presentations of patients with complement abnormalities usually fall into one of the following categories:

- Multi-system rheumatic diseases, such as systemic lupus erythematosus, juvenile rheumatoid arthritis, and Crohn's disease
- Kidney disease
- Hemolytic anemia
- Recurrent or overwhelming infections

"The value of 50"

CH50 testing is the most common assay used to screen patients for the functional activity of the classical complement pathway, and in the work up of complement deficiency. Guidelines from The National Immune Deficiency Foundation and the European Society for Immunodeficiencies recommend screening with the CH50 assay in the diagnostic workup of complement deficiency.[2]

CH50 uses the Classical Pathway and its components of the pathway: C1 through C9. Each of these components is required to be activated in order obtain a normal value indicating that the immune system is effectively eliminating pathogens, damaged cells, etc. The starting point of the pathways is at the C1 complex which recognizes antibody molecules and initiates a cascade. Next is a conformational change allowing activation and cleavage of the next protein in the complement pathway. This is followed by a series of cleavage events—where one protein activates another, which activates another, then another—like a row of falling dominoes—until a protein called C5 convertase is generated. This C5 convertase cleaves complement protein 5 or C5 into C5a and C5b, initiating the formation of the MAC. The MAC is a C5b-9 complex, which can cause pores or holes to form on the surface of the pathogen or cell that the body needs to eliminate, ultimately causing its destruction. It is the formation of these membrane attack complexes that are detected and measured when 50 percent of them are lysed, thus the name "CH50."

How to test for CH50

Presently, there are three methodologies for testing CH50:

1. Hemolytic: an old, complex, and laborious method first described by the esteemed Manfred Mayer in 1958. It uses sheep erythrocytes sensitized with anti-sheep antibodies. Complement activation leads to MAC formation and 50 percent hemolysis of the erythrocytes. Increased complement activation gives increased hemolysis, and the amount of hemoglobin release results in a red color. The more hemolysis, the darker the red color.
2. ELISA: uses a microtiter plate that combines principles of the hemolytic method; hemolysis is measured spectrophotometrically. The assay takes more than 2.5 hours to complete.
3. Liposome: a relatively new method that is an automated assay. The process entails antigen labeled liposomes sensitized by antibodies. The complements are activated by the antigen antibody complex that will break the liposome

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membrane. An enzyme called Glucose 6-phosphtase converts nicotinamide adenine dinucleotide (NAD) to NADH (nicotinamide adenine dinucleotide (NAD) + hydrogen (H)), and the rate of production of NADH is then measured. Test results are available in 13 to 15 minutes on specific automated analyzers.

Because of the different testing methods for the CH50 assay, there will be variances in what is being measured and in the type of units a laboratory will be using. The numerical values across the different methods may not be directly comparable. Causes for the differences in results include the detection technologies, assay optimization protocols, different cutoffs for normal ranges, and specific laboratory conditions.

Integrity is key

Sample integrity is the single most important factor when running the CH50 assay. Since CH50 complement is labile, preserving sample integrity is critical for accurate results. CH50 activity gradually decreases with time and heat. Samples should be frozen, kept on ice, or run immediately.

Future of complement testing

The future is very promising. Great progress has been made in understanding of the quantification and activation of the complement system. Recently, complement has been associated with neurodegenerative disorders, such as Alzheimer's disease, multiple sclerosis and Guillain-Barre syndrome.[3,4] Other complement assays that clinicians may order to look at complement disease associations or deficiencies may include: C1 inactivator, C1q, C2, C3c, C4, C5-9, Factors B, H, and I. Scientists in complement research are continuing to harness the complement system for solutions in the understanding of how complement measurements work in diagnosis of diseases, drug therapies, and solutions for immunodeficiencies.

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Disabilities in the medical laboratory workplace

By Lt Col Paul R. Eden, MT(ASCP), PhD, USAF (ret.)

Laboratory supervisors and their staff members are asked to wear many hats. Working in the blood bank, for example, may have you performing type and crossmatches one day, training new technicians on blood issue policies the next, and preparing your department to implement new lab equipment on the floor the day after that—and in many situations this is all in the same day.

Staff members with disabilities

One of the less common (but just as important) challenges faced by laboratory supervisors is staff members with disabilities. Disabilities present themselves in many forms including mental and physical. Disabilities can make certain aspects of the job challenging not only for the employee, but for a supervisor to position the employee to succeed. Federal law, as well as laboratory accreditation standards, address some of these issues. An advantage we have as laboratory professionals is that in many situations a simple adjustment to the employee's role can help staff with disabilities perform well, while continuing to meet both law and laboratory guidelines and requirements.

The law

The United States Congress passed the Americans with Disabilities Act (ADA) in 1990[1] to address discrimination in the workplace with oversight given to the Equal Employment Opportunity Commission (EEOC). The act states that a disabled person is identified as "physical or mental impairment that substantially limits one or more major life activities."[2] This may include difficulty walking, standing for long periods of time, difficulty in reading laboratory documentation due to dyslexia, or, for example, difficulty drawing blood due to excessive hand shaking. In addition, the law does not allow an employer to treat an applicant or employee less favorably than a healthy employee due to disability. The law goes on to state that employers are required to make reasonable accommodations to an otherwise qualified person.[1] Reasonable accommodations include possible wheelchair access or modifications to normal practice(s) in the workplace. However, the term "reasonable accommodations" can be subjective.

As a supervisor you may ask how far of an accommodation is required to meet the letter of the law. First, an employer is not required to make accommodations that result in undue hardship(s). For example, a technician broke their ankle at home and is unable to climb stairs as a result. As a supervisor, you are not required to move the laboratory instrumentation to the first floor to accommodate the staff member. However, you can direct him/her to the building elevators to accommodate their limited mobility and/or adjust their work assignments to enable the person to work at a desk instead of standing during recovery. The disabled employee should be able to perform the essential tasks of their position. Discrimination based on a disability regarding hiring, firing, pay, work assignments, promotions, layoffs, and training is forbidden under the law.[3] This accommodation is also applicable to laboratory accreditation checklist items.

Paul Eden and his two-year-old service dog, Charlotte; a Great Dane from the Service Dog Project. *Image courtesy of Paul Eden.*

Ergonomic plan

The College of American Pathologists (CAP) general checklist contains both Phase I and II items that are relevant to disabled employees. Environmental Safety (GEN.77200) addresses ergonomic situations in the laboratory in regard to disabilities. This checklist generally covers work-related hazards in the laboratory via the facility's ergonomic plan. The plan should include steps to address disabled personnel. For obvious reasons, a plan can't be written that covers *all* possible disabilities, however, addressing and accommodating staff disabilities is important.

Another common scenario is a disabled staff member experiencing low back and/or knee pain. Typically, implementation of the laboratory ergonomic plan addresses this issue. For example, if a staff member cannot stand on their feet all day, a chair can be provided, or the member can be assigned tasks that enable sitting, such as quality control review, or workload management.

Color blindness

Working in a medical laboratory presents dozens of tasks that require the ability to not only distinguish color but differentiate between colors. Some examples include reading hematology slides, processing microbiology culture samples, and/or measuring color changes in point-of-care tests. As such, color discrimination (GEN.55400) is a standard checklist item that addresses visual color discrimination (color blindness) in laboratory employees.

The ADA states an employer cannot discriminate against an applicant or employee due to color blindness. Also,

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evaluation of an employee is not required if the employee works in a role that doesn't require color discrimination such as administration or documentation management. To work with members with color blindness, a supervisor could delegate the disabled employee to load (identical color blood tube) samples onto an analyzer, or work in the blood bank or urinalysis department.

Evacuation plan

General checklist (GEN.73900) reflects the facility's evacuation plan. If your laboratory employs disabled personnel the evacuation plan, "must cover all personnel, patients and visitors, and must address the special needs of persons with disabilities."[4] There are additional checklist items that impact disabled personnel; however, the examples given are the most applicable to the ADA and disabled personnel.

How to accommodate staff members with disabilities depends on the flexibility of the position and a realistic accommodation of the situation. For example, if a staff member is bedridden due to a medical disability, there may be no reasonable accommodations that can be made. (I doubt that sending blood slides to the member's house to review while in bed would not prevent undue hardship to the lab staff!) Therefore, it is the flexibility to meet the needs of the laboratory as well as the staff member's disability—which is the key to success in this situation.

Wheelchairs

An employee that is either confined to a wheelchair or ends up in one due to an injury presents a challenge to all laboratories. Space is at a premium in any area considered "support" to the medical mission. If the wheelchair bound employee works in a section of the laboratory such as hematology or microbiology, they could be assigned, for example, to read blood slides or micro culture plates from a desk. The lab can also generate a work position or fill a vacant position that utilizes the skill sets of the person while meeting the needs of their disability. Suggested roles could include quality assurance, administration (for an experienced staff member), and/or reception to the phlebotomy room, or entry to the laboratory department.

Service animals

A disabled laboratorian may also be matched to a service dog in order to meet the work position they are assigned to. From a personal perspective, I was diagnosed with stage 4 melanoma in March of 2013. I underwent nine surgeries including four brain surgeries. As a result, I developed a severe balance and dizziness issue. This makes moving around very difficult under normal circumstances. Matching to a service dog through the Service Dog Project has enabled me to perform more actively in the laboratory community, including traveling to conferences.

A valid question that gets raised from time to time is whether or not a service dog can be utilized by a hospital employee. As you can imagine, there are multiple challenges to the introduction of a service dog to the laboratory workplace. These include (but are not limited to) cultural sensitivities, trip hazards, phobias, allergies, and exposure to zoonoses.[4]

Guidelines from the ADA indicate that any non-sterile location (such as intensive care unit or operating room) can be entered by a service dog.[1] A disabled lab technician that requires mobility assistance from a service animal could fill a number of important roles, including a bench technician to read hematology slides, teaching medical laboratory students, performing compatibility matching, and/or any number of regular laboratory testing. Again, if you fit the disabled staff to the right task(s), they will excel; a continual challenge that every lab manager faces with both disabled and non-disabled employees.

The Service Dog Project

The Service Dog Project (SDP) has donated over 150 Great Dane service dogs to mobility impaired individuals to assist them in achieving greater independence. Their working service dogs have been placed with veterans and individuals with Multiple Sclerosis, Parkinson's Disease, Cerebral Palsy, etc. Each dog receives extensive training for balance and mobility.[5]

Why Great Danes? Balance support dogs should be at least 45 percent of the person's height and 65 percent of their weight. This means a 6-foot tall man would need a 30" dog in order to put stability at the person's fingertips. Great Danes are well suited to home and office life. Also, their perfect public persona makes them very conducive to help with the isolation and depression which often accompanies disabilities.[5]

Conclusion

The implementation of the ADA has challenged medical laboratories to productively utilize their disabled laboratorians. This utilization includes meeting accreditation checklist items and ensuring effectiveness of the laboratory staff. Work-arounds discussed for disabled laboratory staff are not comprehensive by any means. If you ask any ten laboratory supervisors, I would bet that each of them could present unique disability challenges faced by their lab during their tenure. Laboratory managers and supervisors must come up with creative solutions that help both the disabled staff member(s) and the laboratory mission as a whole, creating a win-win situation for all parties involved.

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WES vs WGS: why the exome isn't the whole story (and sometimes when it's better)

By John Brunstein, PhD

In this month's installment we're going to revisit in a bit more depth a topic that's been touched on in this space before—that is, the differences between a whole genome sequence (WGS) and a whole exome sequence (WES). On the surface the differences are simple and explicit in the names. WGS provides the sequence of the genomic (nuclear) DNA from a sample, including all sorts of noncoding regions such as centromeres, telomeres, long repetitive stretches of "junk" DNA, and various un-transcribed control regions which influence the activity of the actual genes. For a human, a whole genome is approximately 3.3 billion base pairs, haploid—so 6.6 billion base pairs to capture the whole diploid complement per cell. The exome by contrast is just the collection of expressed RNAs (including both coding mRNAs and noncoding functional RNAs which can be everything from rRNA functional ribosomal components to tRNAs essential for protein expression to things like miRNAs important for gene silencing and post-transcriptional regulation). The human exome is roughly 30 million base pairs total size, or only about one percent of the genome.

Sequencing either a genome or an exome requires collecting a significant "overage" of data, or "sequencing depth." This is done for two reasons: one is to improve accuracy (a single read may misrepresent a particular base pair, so a consensus of multiple reads over the same spot is more accurate) and the other is that to build up full chromosome length reads from short bits requires 'tiling' or overlap between reads so we can generate long contiguous sequences. Since the predominant next generation sequencing (NGS) technologies produce individual read lengths much shorter than many RNA transcripts, tiling is as much a requirement for WES as it is for WGS. Overall then, while there are a lot of nuances we won't go into, while either a WGS or WES requires a lot of data to be generated and processed by bioinformatic pipelines, a WES is to a first approximation 30 fold less data than a WGS (you're excused for expecting that to be 100 fold but WGS tend to be run ~30x depth and WES at ~100x, to allow for capture of rare variants; more on that below). Obviously then WES has one immediate advantage over WGS in that it's faster and cheaper to obtain and analyze.

We generally think of doing some form of NGS in a clinical context as a means to try to uncover the root cause of a particular physical manifestation—a phenotype. We'll ignore the inconvenient reality that some phenotypic behavior arises from complex polygenic traits and assume for simplicity that in this hypothetical example it's a simple monogenic Mendelian cause. Cost and time factors aside, what are the pros and cons of using either a WGS or WES approach to tackling this?

Surprise #1: for complete exon coverage, WGS beats WES

Within protein coding sequences, mutations can in some cases be known pathogenic from other examples, or they may be novel but of readily apparent impact such as stop codons, significant insertions/deletions, or frame shifts. Even less readily interpretable amino acid substitutions may in some cases be scrutinized against known or computer predicted protein structures with a reasonable chance of spotting significantly disruptive changes (putting a proline in the middle of that critical α-helix probably isn't a good thing)! While you might think that mutations in coding regions should be equally observable in both WES and WGS approaches, it's been observed that that's not quite true; in particular, GC-rich gene sequences appear more accurately captured by WGS than WES. WGS also scores better for completeness among preselected panels of disease relevant genes, where WES is reported to miss between 0.42 percent and a whopping 24.44 percent of exonic data as captured in a PCR-free WGS strategy. (For a more in-depth look at these numbers, see e.g. [1]). If complete coverage even just of exons is your goal, then WGS edges out WES.

Meaningful mutations can also occur outside of exons, in regulatory elements such as transcriptional promoters, enhancers, and suppressors thereby altering expression level and/or location. Similarly, mutations within introns can influence splice site selection and lead to inappropriate expression of particular splice variant isoforms of a gene which is otherwise expressed at an overall appropriate level. Since these by their very nature occur in non-transcribed sections of the genome (or at least not retained in mature transcripts), an immediate expectation might be that these will be captured in WGS and not in WES. Strictly speaking that's true; a WGS data set will include all of these sorts of regions but a challenge comes when we try to interpret. Like with exons, in some cases there are very specific variations such as SNPs (single nucleotide polymorphisms) in non-exonic regions which have a known phenotypic impact (or lack thereof). As databases get filled with more and more example human genomes with clinical correlates, the library of known variations becomes bigger. At present, however, compared to the size of the human genome and the frequency with which variations from reference genomes are seen, this known library is small and in

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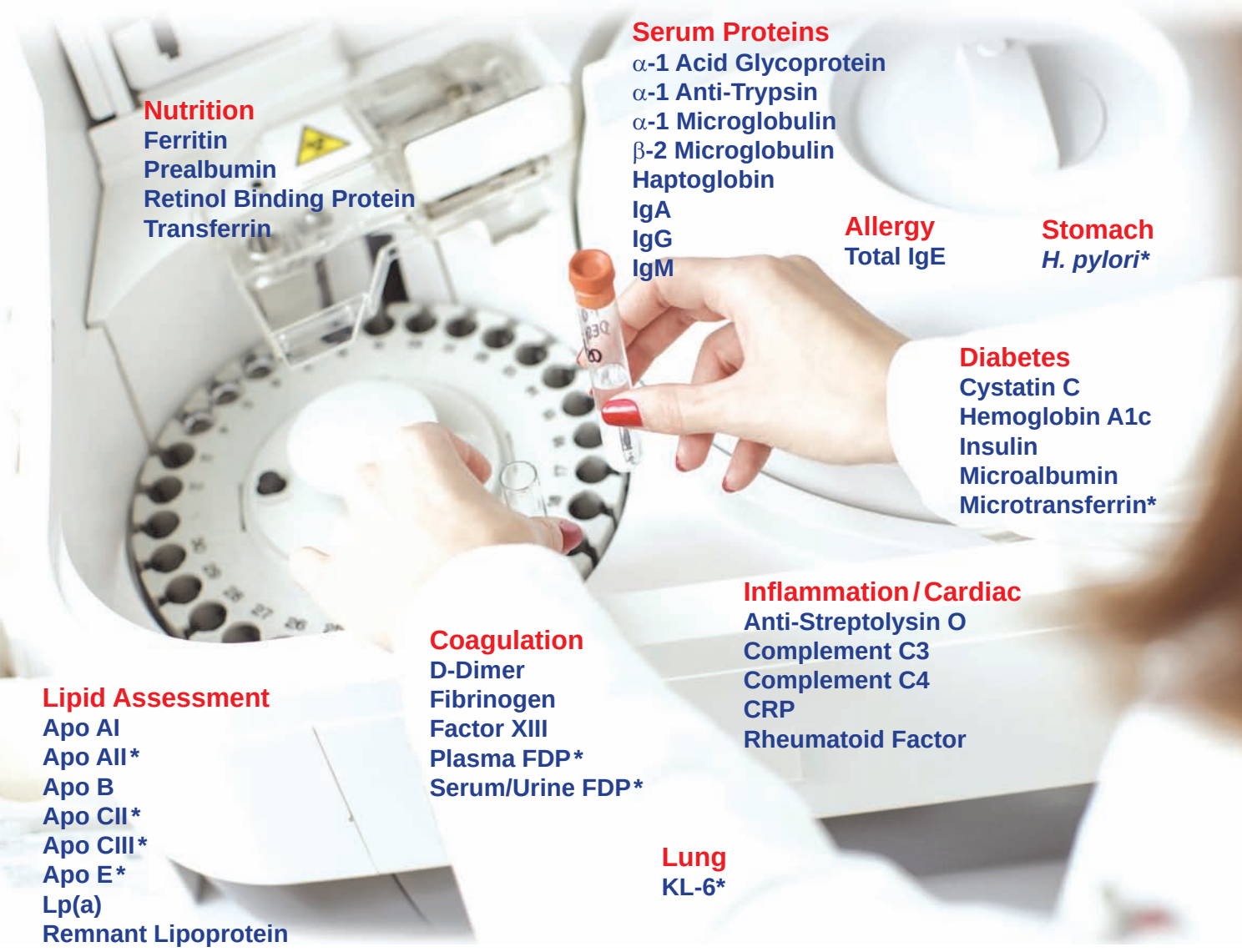

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the majority of cases, variations noted are of unknown impact. These even have their own name "VUS" (variants of unknown significance) and create a number of headaches in clinical practice, not just interpretationally but also with regard to ethical issues about even disclosing them. Particularly if disclosed to non-specialists they're prone to cause misunderstanding (for a more in-depth discussion, see e.g. [2]). By some estimates, each of us is walking around with roughly half a million VUS in our respective genomes. So, while the WGS data captures all of this, we're left in many cases unsure of how to interpret what we have.

Surprise #2: look to the exons if you want to know what happened outside them

Paradoxically, the best approach to find evidence of meaningful non-exonic variation is probably through WES. That's right, we should look at the exons to find out what happened elsewhere. The key here is to remember that a WES is generated from cDNA and includes not just individual sequences but also relative observational frequencies of gene products and even particular splice variants of a single gene. If (and that's a critical caveat) the cDNA library used for WES comes from the cell population of interest, this provides a snapshot not of the actual non-exonic sequences but of their significant effects. For example, in the case of mutations impacting net gene expression level, the impacted gene will represent a lower or higher level compared to expected when referenced to other housekeeping genes in the sample. Where the mutation impacts something more nuanced such as splice site bias in a particular gene, relative levels of gene isoforms will deviate in the sample from equivalent isoform ratios in control samples. While this doesn't give us any information on what the actual root cause mutation(s) is (are), it ignores the impact of truly insignificant variations which we'd otherwise classify as VUS and be left none the wiser.

So, what's better, WGS or WES?

The answer to that depends on what it is you're looking for, and the resources available in terms of time, cost, and bioinformatics tools. WES rose to popularity early on and it remains a cost-effective focused strategy for looking at what is likely to be the most informationally dense set of genomic data from a sample. Bear in mind the comment above though that cDNA populations and their derived WES data sets are tissue specific to some degree. In addition to this they have demonstrated biases against representing some sequence types and can lack the completeness of a WGS. In comparison, PCR-free WGS requires more cost and effort but is more complete in its coverage and is generalizable across the whole organism (we'll pretend this space wasn't just recently devoted to somatic microchimerism as the exception to this). If at some point in the future we have vastly more data such that VUS are a thing of the past, then WGS will probably be the 'better' choice. Before that occurs however, and as costs of NGS technology continues to drop and ease of use increases, we may reach a situation where the most complete and interpretable genomic picture is obtained by capturing both a WGS and a paired tissue-relevant WES. Each provides a slightly different insight to the genome and in reality the two forms of data are complementary.

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John Brunstein, PhD, serves as an Editorial Advisory Board member for MLO. John is also President and CEO for British Columbia-based **PathoID, Inc.**, which provides consulting for development and validation of molecular assays.

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A dialogue with Piper Antimarino, Head of Business Fields - Transfusion Medicine, Ortho Clinical Diagnostics

How did your experience as a Navy lieutenant shape the professional you are today? There are many ways that my years as a Naval aviator shaped me. The biggest things I have carried into my professional career are: (a) Keep the strategy simple; (b) Prioritize the actions that will ensure the success of the strategy; (c) Continually communicate what everyone's role is to ensure the success of the strategy; and (d) Evaluate the effectiveness of the strategy and adjust as necessary.

What path led you to a career in the healthcare industry? I grew up in a family that was involved in healthcare, and in college I studied biology, which is what initially drew me to healthcare after I got out of the Navy. What has kept me in it is that it is a place where I can make a difference. Healthcare has changed dramatically, and healthcare providers are struggling to ensure they are providing the best possible care while controlling expenditures. At Ortho, I feel that we are approaching the issue from a different perspective. We are focused on providing a portfolio that offers our customers efficiency by allowing them to control their inputs, optimize their testing processes, and provide them with trusted results.

Can you give our readers more information about the Ortho neXT Tour? Laboratory professionals and hospital executives are increasingly pressed for time and resources. We have solutions for them but realize they cannot always make it to the big trade shows and conferences to experience our latest products and services. So, we're excited to have put the Ortho experience on wheels and we're traveling straight to their front door.

The neXT Tour is a 46-week tour of labs and hospitals in the United States. It's centered around our next-generation clinical lab solution, the VITROS XT 7600 Integrated System, but it covers the complete Ortho portfiolio, including the ORTHO VISION Analyzer for the transfusion medicine lab, Informatics Solutions for data management, and the company's Ortho Care customer service and support.

Ortho has a longstanding commitment to sustainability. Can you give some examples? A prime example goes right to the heart of our business—and that is our VITROS Systems for the clinical lab. They do not require plumbing to operate, which helps our customers reduce their environmental footprint. Another reason is that VITROS Systems use Ortho's proprietary multi-slide technology, in which a sample is dropped onto a dry, postage stamp-sized slide that contains the reagent.

So, as you can see, protecting the environment and advancing sustainability go hand-in-hand with our purpose of improving and saving lives through diagnostics. We are committed to operating in a manner that supports the environmental health of the communities in which we operate and the sustainability of the planet.

Aside from making water savings easier for our customers, our own practices also are emblematic of our philosophy. If you drive up to our global headquarters in Raritan, NJ, you'll see an illustration of that: acres of solar panels on the front lawn. The solar panels alone offset 2,010,401 kilowatts, which is enough to power nearly 200 homes.

What can you share about Ortho ON DEMAND training programs? This is another area where we're getting closer to our customers. We have been partnering with several customers, as well as key opinion leaders, to bring category trends, topics of interest, and best practices to labs around the world. Ortho ON DEMAND enables us to create a forum for ongoing education that can be delivered any time worldwide.

What are Ortho's predictive technologies and how are laboratorians benefiting from them? Our predictive technologies are centered on our proprietary e-Connectivity technology, which enables us to track how our analyzers and assays are performing and how customers are utilizing them. We have also built a customer portal where customers can log in and see high-level tracking and detailed reports on how their analyzers are performing. With this data, they can focus on how to better control and optimize the laboratory operations and performance. It's part of a wider focus on customer service and support. When you buy an Ortho analyzer, we are ready to offer you the support you need and deserve—and we take pride in that.

There is often a disconnect between sales and marketing teams. How aligned are Ortho's sales and marketing teams and how often do you get to interact with the customer? Alignment and communications are two things that always need to be focused on. Critical to the alignment is everyone being clear on the strategy and everyone knowing their role in contributing to its success. The second part is to see the effectiveness of the strategy and ensuring it is meeting our customer's needs; you cannot do that behind a desk at the corporate office. My team and I travel extensively to customer sites to make sure we understand their goals and challenges and to get direct feedback as to how well we are meeting their needs and where we need to improve.

You work in a very competitive industry. What has Ortho done to focus on quality over quantity? Ortho has always been known for quality and it is ingrained in our culture. Our value proposition focuses on differentiating on efficiency; as such we know that we have to provide a high-quality product to our customers. We utilize our e-Connectivity technology to track and trend how our products are performing in the field and how our customers are utilizing them. With those insights, we have been able to make sure that the specifications of our products and product release testing matches our customers' needs and expectations.

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