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EXCLUSIVE INTERVIEW

Understanding Babson Diagnostics' Hybrid Lab Testing Model

De-centralized sample collection and central laboratory testing

ERIC OLSON, FOUNDER, CHAIRMAN, COO, BABSON DIAGNOSTICS Pages 10-17

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From the Desk of R. Lewis Dark...

THE DARK REPORT

RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTs

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COMMENTARY & OPINION by...

R. Lewis Dark

Founder & Publisher

Innovations Might Reduce Need for Phlebotomists

ALREADY A SERIOUS PROBLEM PRIOR TO THE PANDEMIC, the shortage of trained phlebotomists continues to grow more serious with each passing month. Some clinical laboratories are offering wages of $25 per hour or more and say they cannot attract enough candidates to hire and train for this essential role.

However, there is a company developing new technologies and a different model of lab testing that would allow any individual to collect capillary blood specimens using a novel device. The good news is that, once this device reaches the market, it could significantly reduce the need for phlebotomists to collect venous blood specimens. But much must happen before this vision becomes reality.

The company is Austin, Texas-based **Babson Diagnostics**. Although it will require more time for Babson to finish development of these technologies, acquire regulatory clearance, and launch its service in the marketplace, it has the potential to be a positive disruption to the status quo in the collection of clinical laboratory specimens.

This company and its vision for launching a new hybrid model that involves decentralized sample collection and central lab testing was showcased at last April's *Executive War College* in New Orleans. Responding to its survey of consumer likes and dislikes about different aspects of laboratory testing, Babson designed the device to play to consumers' preference of convenient blood draw locations and greater comfort during the procedure. *(See our coverage starting on p. 10.)*

Babson's hybrid approach is one more example of how an emerging company has, as its primary goal, introduction of a better solution to existing products and workflow involved in collecting, processing, and testing clinical laboratory samples. The company wants to flip the model of blood collection from one of centralized draw stations, such as around a hospital campus, to one of decentralized draw sites, such as at retail pharmacies. Pharmacy staff would collect lab specimens, which lessens the need for hard-to-find phlebotomists to draw the blood. In this amended approach, the samples are still sent to a centralized laboratory for analytics.

This isn't to say that Babson's technology will be a home run with laboratory buyers. But it is certainly ambitous to want to disrupt the long-standing method of using trained phlebotomists to collect venous blood. TDR

VALID and SALSA Acts Still Pending in Congress

Race is on to address lab test pricing cuts, regulation of LDTs, and physician fee changes

Erin Morton

CEO SUMMARY: Both the pending VALID Act and SALSA Act continue to push ahead as 2022 comes to an end. Meanwhile, a new bill centered on the Physician Fee Schedule may protect pathologist payments. These three different proposals share something in common: To pass this year, they need to be part of a larger spending bill that will likely go before Congress in December.

THREE LABORATORY-RELATED PROPOSALS are seeking ways to get attached to a larger spending bill that will go before Congress by year's end, though nothing is guaranteed for any of them. Observers are eyeing the status of the following proposals:

- Verifying Accurate Leading-edge IVCT Development (VALID) Act, which seeks to move oversight of laboratory-developed tests (LDTs) to the **U.S. Food and Drug Administration** (FDA).
- Saving Access to Laboratory Services Act (SALSA), which aims to reduce lab test reimbursement cuts already called for under the Protecting Access to Medicare Act (PAMA) of 2014.
- The new Supporting Medicare Providers Act, which would temporarily reduce cuts to the Physician Fee Schedule, including to pathology services, that will go into effect in 2023.

Recent mid-term election results will have little influence on VALID Act or SALSA, said Erin Will Morton, Partner at **CRD Associates** in Washington, D.C. Morton represents the **National Independent Laboratory Association** (NILA) in legislative matters. Rather, the lab proposals will compete with other priorities to get added to the year-end spending bill.

"Regardless of what happened with the election, policy makers will want to come back in January and start fresh," Morton said. "So, I think they want to get a year-end spending bill out of the way before the end of this year."

Of immediate concern to clinical laboratories and anatomic pathology groups are reimbursement cuts of up to 15% for 800 laboratory tests. These price changes are set to occur on Jan. 1 under the PAMA statute.

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SALSA seeks to halt the severity of those decreases by taking three actions:

- Eliminate scheduled Jan. 1 price cuts.
- Implement caps on future payment decreases to the Medicare Part B Clinical Laboratory Fee Schedule (CLFS).
- Reconfigure how federal agencies calculate lab test payments for the CLFS.

"We're having conversations with congressional committee staff and the bill's sponsors about including SALSA in the year-end package that gets put together," Morton said. "However, anything that gets put into that year-end bill needs to be paid for."

If SALSA does not make it into a spending bill in December, the PAMA cuts would remain for Jan. 1. *(See TDR, "PAMA Cuts Might be Reduced to Zero for 2023," Aug. 8, 2022.)* Under those circumstances, lab industry associations would try to negotiate another short-term delay in pricing cuts, Morton noted.

VALID Act's Focus on LDTs

Currently, LDT approval comes via the Clinical Laboratory Improvement Amendments of 1988. The VALID Act aims to instead require LDT developers to submit an FDA application and related clinical data, with some exceptions.

NILA, which Morton represents, has expressed concerns about provisions within the VALID Act, as have other laboratory organizations. Among the biggest worries is that it would stifle LDT innovation at labs because of the cost associated with FDA review.

On the other hand, champions of the VALID Act feel LDTs are akin to medical devices and thus should undergo pre-market approval by the FDA to protect patient safety.

The Supporting Medicare Providers Act was introduced in September to combat cuts to the Physician Fee Schedule. "Estimates indicate the overall impact to pathology payments from 2022 to 2023 would decrease by 1%," the **College of American Pathologists** (CAP) noted earlier this year. Part of the cuts are due to the expiration of a one-time increase in physician payments passed by Congress in late 2021.

New Bill Is Shorter

The new bill is short and would simply amend dates to avoid reductions in reimbursements to physicians. The proposal does not represent an overhaul to the Physician Fee Schedule.

Lab professionals who have strong views on any of these proposals still have time to express their opinions to their senators and representatives, which could influence whether they get attached to the larger spending bill. TDR

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Important Lab Bills Pending in Congress

HERE IS A RUNDOWN of pending legislative action that could affect clinical laboratories and pathology groups:

- Saving Access to Laboratory Services Act (SALSA—S.4449) aims to permanently reduce scheduled cuts to lab test pricing under the Protecting Access to Medicare Act of 2014 (PAMA) and adjust how pricing data is reported by labs to the federal government.
- Supporting Medicare Providers Act (H.R.8800) attempts to reduce cuts to the Physician Fee Schedule, including to pathology services, that are scheduled to go into effect in 2023.
- Verifying Accurate Leading-edge IVCT Development Act (VALID Act—S.2209) seeks to move oversight of laboratory-developed tests from the Clinical Laboratory Improvement Amendments of 1988 to the U.S. Food and Drug Administration.

Use This 5-step Process to Implement a New LIS

Experts working daily to help laboratories install Epic's Beaker share lessons learned, what to avoid

Robb Quiller

CEO SUMMARY: Rolling out a new laboratory information system (LIS) is a costly, time-consuming project. One expert outlines five steps that clinical labs can take to alleviate pressures while ensuring the right people are onboard to help the endeavor move forward. Among the steps is the need to establish an analyst team to act as a liaison between IT and clinicians.

EACH YEAR, HOSPITALS THROUGHOUT THE NATION using **Epic** electronic health record (EHR) systems transition away from their current laboratory information system (LIS) and implement Epic's Beaker LIS.

Hospital laboratories switching from one LIS to another know that this process can be turbulent and can cost hundreds of thousands of dollars in licensing, training, and maintenance costs over the long term. Moreover, it is critical to laboratory operations that the new LIS be installed correctly.

One LIS company at ground zero in this trend is **Honeydew Consulting**, based in Sacramento, Calif. Many team members know Beaker well because they formerly worked on that product while employed by Epic.

"Any new LIS is going to be the most disruptive project that a lab will experience," said Robb Quiller, Honeydew's Founder and CEO. During an exclusive interview with THE DARK REPORT, he described best practices for a successful LIS conversation and started with three actions lab administrators should take before installing a new LIS:

- Determine decision-makers for the roll-out of the new LIS.
- Establish an analyst team to bridge technology and clinical needs within the laboratory and throughout the parent organization.
- Map current and future diagnostic test workflows to understand how the new LIS fits in with lab processes.

STEP ONE: Assign Advisors to Guide the Project

"One of the first steps is to establish a governance structure for the transition that outlines the business goals of the project and connects those objectives with IT strategies," Quiller stated.

"This structure should include an advisory board that will provide expertise about lab operations for the software build team," he noted. "Typically, these advisory boards are semi-autonomous. They know the workflows. They know the system. They know the clinical content."

Quiller recommended keeping the workgroups small. "Labs don't always need to have large meetings that pull in the whole Beaker team, for example.

Instead, smaller meetings can help build rapport between the advisory boards and build team members," he added.

It's also important to clearly identify which individuals to approach when problems arise. "Labs should spell this out and write it down," he said, especially in larger organizations.

In addition, Quiller noted, laboratory leaders should clearly identify decision-makers for different areas within the organization and be sure those individuals are held accountable.

Contracted work should be spelled out in this step as well. For example, every Beaker installation requires a third-party contract for middleware that allows instrumentation to interface with the LIS.

"Those middleware contracts should be signed early on," Quiller advised. He cautioned that if contracting becomes a drawn-out process, it is likely to delay other critical tasks and could derail the LIS implementation project in its earliest stages.

STEP TWO: Link the IT, Vendor, and Clinical Teams

Months of planning, perhaps even years, go into an LIS rollout, involving staff members and managers who devote large amounts of time to the project. Given the national shortage of pathologists and medical technologists, setting aside resources for an LIS project is mandatory, though challenging.

"Resource allocation for a Beaker implementation is a big aspect early on," Quiller said. "Everyone has their bandwidth compromised. Part of the problem is that resource allocation isn't just the IT team. Operational and subject matter experts [SMEs] need to be involved to a high extent. Their buy-in and involvement is pivotal to success."

Much of the work of implementing the new LIS will fall to an analyst team that serves as an intermediary between the SMEs and the LIS vendor. The team should be well-rounded and include members who are familiar with clinical issues, the legacy LIS, the lab's hardware devices, and reports generated by the laboratory.

"Too often, labs will have an IT team without a ton of clinical background or, conversely, people with a lot of clinical background, but no IT experience," Quiller observed.

Beaker, he said, is part of the integrated Epic EHR system, so the build may be part of a large workflow that includes placing lab orders, collecting specimens, and reporting results.

This means that the LIS will have impacts beyond the lab itself. Therefore, the analyst team should include members who can address where an LIS installation overlaps with other areas in the hospital or health system, such as ordering, billing, and ambulatory care.

STEP THREE: Map Lab Workflows and Data Exchanges

Laboratories should build flowcharts that illustrate current work processes. This will help the analyst team understand the current state of operations and identify pain points that can be improved with the new LIS, Quiller recommended.

By comparing legacy LIS processes with flowcharts for the new system, labs can identify areas where staff might require new training, he noted.

One tipping point for many labs involves receiving data exports from the legacy LIS—such as reference ranges—and rebuilding them in the new LIS.

"Many times, these exports are heavily coded," Quiller explained. "The information needs to be in a usable format and well understood." The analyst team, he added, should be prepared to work with the SMEs to bridge the communication gap between the legacy LIS and the new Beaker LIS infrastructure.

Labs also must account for instruments and devices that will interface with the new LIS. The rollout benefits if labs use the same software drivers. But Quiller

Time-Tested Steps to a Winning Beaker Install: Anticipating Common Problems, Positioning Experts

MUCH CAN GO WRONG when a new laboratory information system (LIS) goes live. The ability to rebound from these temporary problems rests with the earlier preparation work of lab staff, vendors, and consultants.

"Going live with Epic's Beaker or any new LIS is not the end, it's the beginning," said Robb Quiller, Founder and CEO at Honeydew Consulting. Labs can expect periodic software updates, system upgrades, and new functionality. And they may have to perform optimizations they delayed until after launch.

Immediately after going live, labs should focus on key performance indicators. "Look at the overarching themes. How are the billing charges doing? Are the test turnaround times sufficient?" Quiller noted.

Once a system goes live, it is important to have personnel on hand to provide needed assistance, including people responsible for data migration and middleware support. Generally, support personnel should be available for night shifts as well as day shifts. "Vendor contracts should also specify some level of support as a safety net," he suggested.

Lab leaders should clearly define how to escalate a problem so that staff members know the appropriate people to approach when roadblocks or other issues arise. Labs must also establish an approval process for going live with specific parts of the system. "It's good to outline what needs advisory board approval and what needs to just go through a manager," he said.

Provide Adequate Resources

The final stage is what Quiller described as "post-live stabilization," and, as with other aspects of the LIS buildout, labs must assign adequate resources to make it work.

Lab leaders should avoid "silos of knowledge"—for example, making only a small group aware of reporting problems—and be sure that documentation can be easily shared and accessed across the organization.

"As much as possible, staff should be cross-trained so everyone has a working knowledge of how to troubleshoot issues, avoid certain bottlenecks, and maintain the system better in general," he advised.

advises labs to have a cut-off phase for bringing on new equipment, if possible.

"Adding an instrument to the legacy system just to take it down and bring it back up in Epic can derail a lot of resources," he said.

STEP FOUR: Determine What LIS Features Work Best

Pre-built functionality in an LIS may not address all the needs of customer labs. Instead, the system's foundation serves as a jumping-off point.

"Epic Beaker recommendations certainly are helpful, and they can be accurate maybe 80% of the time," Quiller observed. "But this still means one out of every five recommendations is not going to be right for a particular lab."

Lab managers and pathologists should investigate which features offer the right fit for them, he advised, and determine how the system can be configured to accommodate their lab's processes.

Tied to this notion, labs will likely have to rethink some aspects of how they currently operate. "For example, lab managers won't just take a report from the previous system and build the exact same report in Epic," Quiller said. "Instead, they'll want to think about what need that report satisfies, and how do they address that with the Epic LIS tools?"

This is one area where advisory workgroups and SMEs can be helpful. "The build team should have a strong relationship with workgroups and SMEs so they can ask questions and escalate concerns," he added. This type of interdisciplinary cooperation is also useful for post-live monitoring and discussions about future software adjustments or upgrades.

STEP FIVE: Test Software Functions and Train Staff How to Use the LIS

Testing the features of an LIS, and then preparing to educate employees about its functions, will go smoother if the steps noted above are carried out carefully.

"An emphasis on a good build is going to create more streamlined testing and training," Quiller said.

For example, one of the most time-consuming aspects of a Beaker implementation is clinical content validation, in which the lab ensures that clinical data in the system meets Epic's standards.

"It's incredibly important to do this early and often during the build phase," he advised.

Part of this involves testing the clinical lab's workflow "from the beginning on an instrument to when the results come back," Quiller added. This work can be especially time consuming for SMEs, he cautioned.

Labs also must test the LIS' charging and billing functions, interface connectivity, integration with other applications, and label printing. Quiller warned that labs have struggled with printing because some instruments are better than others at scanning printed barcodes.

Aside from formal training from vendor representatives, some staff will emerge as "super users" who can assist others in learning the system. Lab managers should identify these internal champions early, he said.

Quiller also advised labs to create tip sheets on how to navigate difficult areas of the system, or aspects that deviate from the legacy software.

Additionally, staff should become well-versed in the ticketing system through which they will alert IT personnel to any problems with LIS functions and receive technical support.

"Many times, the information that comes across in these tickets is insufficient and requires follow-ups to figure out the issue," he noted.

Two essential elements of any LIS support ticket are the specimen ID and a direct call-back number for the person who filed the request. The specimen ID, he said, is "linked to all information pertaining to the progression of the specimen, including the order and results."

Quiller advised labs to be mindful of the date they choose for switching between the legacy system and new LIS. Do not, he cautioned, schedule the transition if a large amount of staff turnover is imminent or a visit from **The Joint Commission** or **College of American Pathologists** is expected.

"With a newly installed LIS, staff might not be clear on how to pull up quality control reports or other required documentation," Quiller noted. "These are lapses which may grab the attention of an accreditation surveyor."

➤ People Key to LIS Success

Taking the five broad steps above will not guarantee success during a laboratory information system implementation. However, these critical steps will help clinical laboratory managers and staff think more clearly about their lab's process and data needs so as to better prepare LIS users for problems.

Quiller further observed that one common element to successful Beaker implementation is when laboratory-based champions can be identified who are capable of bringing the LIS project forward while maintaining their regular duties. TDR

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Crisis Management Update

Florida Hospital Laboratory Team Prepared before Hurricane Ian

With Hurrican Ian approaching the west coast of florida on Sept. 28, hospital laboratories in the predicted path scrambled to be ready for the worst. That was true at **Tampa General Hospital**, where the hospital's clinical lab team went on high alert.

Angela Lauster, Senior Laboratory Administrative Director at 1,041-bed Tampa General recounted steps the lab took to brace for the storm. "Our hospital lab designated two teams for hurricane staffing," she said. "Team A was onsite during the storm, while Team B relieved the other group once Ian blew by."

Staffing Coordination

As such, members of Team A—including Lauster—stayed at the hospital for three days straight. Team A designees needed to be comfortable leaving their families, homes, and pets behind for several days.

Caring for those lab workers onsite was paramount to Lauster. "The lab made sure that employees still got their nutrition, that they were hydrated, and that they had a quiet place to sleep," she explained.

She got creative with spaces to sleep, thanks in part to the pathologists. "We have 13 pathologists, and only one of them came in and worked during the storm as the on-call pathologist," she recalled. "So, the other pathologists loaned their offices to the lab for Team A sleeping.

"We created a schedule where, during a given 12 hours during the storm, one person had a pathologist's office. Then, during the next 12 hours, another person had the office," Lauster added. "We also took our medical residents' room and converted it into sleeping quarters. Similarly, we took our conference room and converted it into sleeping quarters."

As lab director, Lauster is always on Team A and she ensures that at least two of her eight managers also are on that team. "I make sure I've got enough managers here during an event, so that if I need extra leaders to help, the hospital is covered," she said.

Air Conditioning Advice

Tampa General is located on Davis Island in Tampa Bay, with two roads into the property. Flooding and power loss have long been concerns during storms.

Earlier this year, the hospital opened a new power plant 33 feet above sea level that is designed to withstand Category 5 hurricane winds. While smaller hospitals and medical labs may not be able to afford such actions, the forward thinking of Tampa General in relation to its location is an activity other sites can emulate.

From a practical sense, Lauster offered a tip to all labs that rely on air conditioning to keep instruments cool: Ensure that A/C is either always tied into emergency power lines or that hospitals have a plan to bring in portable air conditioners that can tap into power generators.

"Labs sometimes forget that air conditioning is not always attached to emergency power," she said. "Clinical labs must be thinking about this and planning year-round. Labs can't do it a week before an emergency event." TDR

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Goal is to serve customers by collecting small samples in retail pharmacies

Babson Diagnostics' Hybrid Model Combines Quality, Convenience

Eric Olson, PhD

CEO SUMMARY: Responding to its own data about consumer preferences, healthcare technology company Babson Diagnostics is pursuing a new hybrid model for blood draws that it believes brings together the best of clinical laboratories and retail pharmacies. Laboratory managers and pathologists may find opportunities in such an approach.

Two emerging trends have the potential to significantly alter the clinical laboratory industry in fundamental ways. Moreover, a young diagnostics company in Austin, Texas, is working to deliver new technologies it hopes will accelerate the adoption of these new trends.

One trend is to bring specimen collection services closer to the growing number of customers who are moving from conventional patient service centers (PSCs) operated by clinical laboratories to alternative collection sites, particularly retail pharmacies. The second trend involves using technology to create a new collection method that:

- Is friendlier to patients,
- Requires much smaller quantities of samples, and,
- Can be used by labs to deliver accurate, reproducible results using most existing analyzers.

These trends are consistent with the expectations of today's informed healthcare consumer. These consumers want personalized care, convenient access to medical services, transparency in quality, along with digital access to scheduling and clinical laboratory test results.

The diagnostics company that wants to be at the intersection of these trends is **Babson Diagnostics**. Founded in 2017, it has raised more than $44.6 million from investment groups that include **Siemens Healthineers**.

Clinical laboratory administrators and pathologists interested in keeping their respective labs' strategies tuned to the realities of today's healthcare marketplace will find it useful to understand Babson's market predictions and the diagnostic technologies it is developing.

At last spring's *Executive War College Conference on Laboratory and Pathology Management*, Eric Olson, Founder, Chairman, and Chief Operating Officer at Babson Diagnostics explained the innovations unfolding at his company in a presentation titled, "Clinical Lab Services for Today's Healthcare Consumer: Delivering Value with Accessibility and a Better Collection Experience."

The intelligence briefing that follows is organized around the primary topics about which Olson spoke during his presentation:

- **Consumers and Site of Service:** Why moving specimen collection into retail pharmacies and similar settings better meets the expectations of today's healthcare consumer while also benefitting clinical laboratories.
- **New Hybrid Collection & Test Model:** Babson explains the hybrid model, which decentralizes specimen collection and centralizes the testing of the specimens.
- **New Specimen Collection Technology and Devices:** How an alternative method for capillary blood specimen collection improves the patient experience and reduces the volume of sample required for many types of basic clinical laboratory tests. Equally important, why it will reduce the need for trained phlebotomists, including an overview of the clever designs of the different products under development to enable collection of smaller samples and their testing at the lab.
- **Centrifugation of Smaller Samples for Testing by the Clinical Lab:** What is required for high volume laboratories to analyze the smaller quantities of capillary blood samples while maintaining accuracy.
- **Validation of Lab Assays Using Capillary Blood and Tested on High-Volume Analyzers:** Babson's team is conducting the validation studies necessary to demonstrate that capillary blood samples collected with the company's technology consistently deliver accurate, reproducible results when tested by high-volume instruments.

Before proceeding, it is useful to note that the trend of consumers preferring to access services located in retail pharmacies and grocery stores is now in its sixth year. The Dark Report was first to recognize this trend and explain why, going forward, clinical laboratories would need to put PSCs in retail stores throughout their service area if they were to remain competitive. *(See TDRs, "PSCs in Safeway Stores Popular with Consumers," Oct. 17, 2016, and "Labcorp, Quest Diagnostics Open PSCs in Retail Stores," Oct. 30, 2017.)*

➤TOPIC ONE: Consumers and Site of Service

This fast-moving trend is fueled by a simple fact: patients and consumers prefer to go to a retail store near their home or office to have their blood drawn. Experience shows

that when a lab opens a PSC in a retail pharmacy or grocery store, that PSC's appointment book fills up rapidly. The additional benefit to the lab from a busy PSC is that it increases the phlebotomists' productivity and lowers the cost of collecting lab specimens.

Today's consumers have high expectations for service. For example, over the past 10 years, there have been dramatic changes in how consumers purchase retail items and how those consumers travel. In retail, relevant examples are **Amazon**, **eBay**, and **Carvana**. In the travel industry, companies such as **Expedia**, **Uber**, **Lyft**, and **Airbnb** have been in the forefont of delivering personalized options.

In the same fashion, consumers have subsequently reset what they want from primary healthcare providers.

"Consumers expect that things be made simple and be put on their phones," noted Olson during his presentation at the *Executive War College*. "They want to interact with every service in the most convenient way possible. We see that across all industries. The consumer experience has become an e-commerce experience. This holds true for how consumers want to access lab testing services."

Observant lab managers and pathologists will recognize Olson's points. Healthcare consumers—particularly those under 40—want a smooth, fast, and easy experience with retail and service providers, including clinical laboratories. *(See TDR, "Millennials Set to Reorder Healthcare and Lab Testing," May 3, 2021.)*

New Testing Solution

Babson Diagnostics is working with **Becton, Dickinson and Company** (BD) and **Siemens Healthineers** on a new testing solution using capillary blood samples collected at retail pharmacies.

"During consumer preference research we conducted, we learned what consumers and patients value and prefer," Olson said. "Overall, results pointed to a desired change in how blood is collected.

"Accuracy of diagnostic test results was the most important factor to those surveyed, followed by customer service and short wait times," he continued. "Costs and financial issues are also important, but not at the level of being treated well and getting accurate test results."

Opportunities to increase customer satisfaction, according to Babson Diagnostics' data, come from friendly service, evening and weekend appointments, walk-in access, and quick results.

Collection Location, Method

Meanwhile, 85% of consumers who experienced Babson's collection method preferred the pharmacy as a blood collection site over more traditional settings—such as a patient service center or physician's office. Reasons cited include a better overall experience at a pharmacy, staff professionalism, and proximity to home.

These findings corroborate trends that the SARS-CoV-2 pandemic accelerated regarding the influence of retail healthcare locations. Patients continue to recognize the convenience and time-savings of going to a retail pharmacy for services over a hospital or physician's office.

Olson also theorized that retail sites are more in tune with customer service. "The retail pharmacy is much closer to where most patients live and work than a doctor's office," Olson stated. "Retail pharmacies are also a place where employees are trained in customer service. It is part of the DNA of these companies to treat customers right."

Further, Babson found that 81% of those who experienced Babson's collection method preferred the capillary blood collection method over venipuncture. Reasons cited include capillary collection being less invasive, avoidance of vein collection difficulties, and quicker and less painful draws.

"The biggest concern we heard from customers about venipuncture is the anticipation of the needle," Olson commented. "The next biggest concern is being able to see the blood. The overarching theme mentioned by patients is the feeling of invasiveness when lab specimens are collected.

"To alleviate these patient concerns, Babson developed a next-generation fingertip capillary blood collection device in partnership with BD," he added. "That device is for use by a non-phlebotomist to collect blood from the patient's fingertip. The sample is stabilized at the pharmacy, using a sample preparation device that automates all of the pre-analytical processes for blood testing.

"This technology will de-skill the process of blood draws," Olson continued. "The collection process is now in the hands of somebody who works at the pharmacy counter. There's no longer the need to rely on a dedicated, highly skilled phlebotomist."

Pharmacy Blood Draws

Babson's innovations are designed to enable blood draws to simply become another healthcare service offered by the pharmacy. "In addition to filling prescriptions and doing vaccinations, pharmacy staff will also be able to perform blood draws," Olson explained.

This model, if successful, would reduce the bottleneck for blood draws caused by a limited number of phlebotomists and potentially change the hiring environment for this job.

TOPIC TWO: *New Hybrid Collection and Test Model*

Olson next explained that this approach is not rapid testing because the specimens go to a core laboratory for analysis. "Our business model is not point-of-care testing," he emphasized. "It is 'distributed collection' where the sample goes

How Babson Diagnostics' Hybrid Model Works

HERE IS HOW BABSON DIAGNOSTICS' BLOOD TESTING SYSTEM works, according to Founder and COO Eric Olson.

Tests are ordered digitally: Clinicians submit test requests through an electronic medical record portal and customers place test orders online. Customers choose their preferred pharmacy location, pay online, and supply insurance information. Both the customers and clinicians receive results within 48 hours.

Pharmacies serve as collection sites: A pharmacy technician collects a pea-sized blood sample from the customer's finger. The capillary blood collection device attaches to a person's fingertip and works with reverse centrifugation as opposed to conventional centrifugation, Olson said. It is designated as an investigational device by the U.S. Food and Drug Administration, and "requires additional studies to make any definitive conclusions about safety or efficacy," according to a news release.

"The top of the device is squeezed to take blood from the fingertip. No vacuum force is applied. Blood flows down and out of the incision, and comes to the bottom of the device's tube," Olson explained. "It is a device that can easily be used by a non-phlebotomist."

The sample preparation device, about the size of a desktop computer tower, includes a caddy that holds the supplies needed for the procedure.

"The pharmacy team member collects the blood sample, takes the tube off the collection device, and deposits it in the sample preparation device, which automates the labeling, accessioning, sample mixing process, clotting, centrifuging, and refrigeration of the sample," Olson said.

Central labs analyze the samples. Samples are brought from the collection site to a central laboratory for analysis on high-volume analyzers.

back to a high-complexity laboratory with high-throughput equipment incorporating state-of-the-art methods overseen by laboratory professionals.

More Convenient Process

"The laboratory then reports that result to both the customer and the clinician that ordered it," Olson noted. "This is our approach to making blood collection a more convenient, pleasant process.

"It is important to recognize that this is a new hybrid collection and testing model," he added. "Our business model decentralizes the collection process and centralizes the analysis process."

Babson's hybrid model also seeks to address lab preanalytical errors. For example, one common problem is mislabeling collection tubes before patient draws. Babson's process may sidestep that pitfall by using tube barcodes pre-printed on the container itself. With this option, staff do not need to print and place sticker labels on tubes at collection time.

"Pre-printed barcodes are applied irreversibly by the manufacturer with a tube number that gets digitally matched to the customer at the time they present to get tested," Olson said. "So, the sample is married in a very different way. There are no stickers in this process. There are no opportunities for mislabeling. The tube is scanned before the collection and after the collection to confirm the right person is matched to the right tube.

Automated Sample Prep

"Our technology is designed for simplified automated sample preparation," he continued. "There won't be the need to have someone timing the clot. Nor will there be the need to have someone starting the centrifuge. The benefit is less cost and reduced turnaround time.

"The beauty of this distributed collection model is that the high unit cost of a point-of-care test is avoided because these specimens go into the central laboratory, where tests can be performed for 10, 20, or 30 cents. This plays to the strengths of core labs.

"Babson Diagnostics is not here to disrupt the laboratory," he noted. "Babson is here to build on the strengths of what makes clinical laboratories great. Labs have the best quality available, the lowest cost structures available, and the professional oversight that's needed to have confidence in the results the clinical laboratory delivers."

TOPIC THREE: *New Specimen Collection Technology and Devices*

There are three technology and design innovations that are fundamental to Babson's hybrid model of clinical laboratory testing:

- First is a novel specimen collection device.
- Second is a novel automated "sample preparation device" for use in the pharmacy or retail location.
- Third is a novel centrifugation technology that enables high-volume laboratory analyzers to run small capillary blood samples.

Collection Device: The collection device is designed to fit over the patient's fingertip in such a fashion that the patient will see neither the needle nor the blood that is collected.

Sample Preparation Device: The sample preparation device is to be used by pharmacies to automate all the processes required before delivering the sample to the central laboratory for testing. Babson believes this will improve specimen quality and integrity.

"This device automates the sample mixing process. It tracks the sample to make sure it's clotted for exactly the right amount of time and then automates the centrifugation process. It has refrigeration to control the storage temperature and it has transport carriers," Olson explained.

By 2027, Financial Analyst Predicts $8 Billion Market Value as More Primary Care Shifts to Retail Pharmacies

PRIMARY CARE CLINICS IN RETAIL PHARMACIES AND GROCERY STORES may soon be known as "retail clinics," and it is a market that is projected to grow to as much as $8 billion globally by 2027. What is noteworthy here is that industry analysts are beginning to study this emerging section of healthcare in the U.S.

"These clinics are located in easily accessible places, including malls, shopping plazas, and stores," according to **The Insight Partners**, a business research firm that released a report on the retail clinic market in November. "They are ideal to treat acute health issues such as sinus infections, strep throat, urinary tract infections, flu shots, bronchitis, ear infections, ringworm, and immunizations, which are simple to diagnose."

Taken in tandem with our briefing about **Babson Diagnostics'** hybrid approach to blood draws at retail pharmacies, this latest news about the retail clinic market points to a large opportunity for clinical laboratories and pathology practices looking to expand their reach in local communities.

New Consumer Preferences

By The Insight Partners' estimates, the retail clinic market was worth $3.4 billion in 2018 and may grow to $8.1 billion by 2027—a 138% increase over a nine-year period.

Changing consumer preferences on how and where to receive primary care services plays a large part in the growing phenomenon, said The Insight Partners.

Although not noted by the research firm, the fallout from the SARS-CoV-2 pandemic also heavily influenced the market for primary care in retail sites because patients became more accustomed to seeking tests outside a hospital or physician's office.

Few healthcare leaders have established relationships with retail sites that offer primary care services, according to findings from the **New England Journal of Medicine Catalyst Insight Council** published in October and reported on by the **American Hospital Association** (AHA).

"Despite the growth of retail health clinics, only 15% of respondents own or have a formal relationship with these outlets; another 10% say their organization is planning an affiliation within the next three years," the AHA noted.

Retail Options Expand

Meanwhile, some retail chains are aggressively pursuing healthcare offerings. For example, in October, **Walmart Health** announced it would open 16 new health clinics in Florida by fall of 2023.

Walmart Health has 32 clinic locations in Arkansas, Florida, Georgia, Illinois, and Texas. The clinics—which are located next to Walmart stores—offer primary care, laboratory tests, X-rays, behavioral health services, dental, and select specialty services. The Florida expansion correlates with population growth in the state.

"As the population in Florida continues to grow at more than double the rate of the rest of the United States, so does the need to increase access to quality healthcare," said David Carmouche, MD, Senior Vice President of Omnichannel Care Offerings at Walmart in a press release.

Walmart and other companies such as **CVS Health** and **Kroger** are operating as a cog of a larger effort to control a revamped healthcare industry, said columnist Robert Pearl, MD, on the *KevinMD.com* site.

"To dominate all of healthcare, [retailers] can't be reliant on (or held hostage by) any of the legacy players," Pearl noted. "Instead, they want their own pharmacies, health insurance plans, clinics, and physicians."

"So, it's automating all those steps at the pharmacy, because if you de-skill the collection process, but you don't de-skill the preparation process, you still encounter the same bottlenecks. This is why we've made the preparation step completely automatic.

➤Collecting the Sample

"Thus, the pharmacy technician collects the blood sample, takes the tube off, puts it in this device and it automates the remaining processes," Olson noted. "The pharmacy techs do not need to think about those processes once the sample is loaded.

"Our risk analysis involved studying different steps that happened during the preanalytical phase—the errors that happen, the frequency, the detectability, the impact of those errors," he said. "That helped us identify which errors we can mitigate and which ones we cannot."

Centrifugation Technology: Because the sample is of capillary blood, Babson faced the challenge of how to centrifuge it and deliver it to the high-volume analyzer to reduce wasted sample volume and avoid gel clogging the instrument probe.

➤TOPIC FOUR:
Centrifugation of Smaller Samples for Testing by the Clinical Lab

To allow the smaller volumes of capillary blood samples to be tested in high-volume laboratories, engineers developed special centrifugation technology.

"Because high-volume analyzers are designed to run with big samples, we had to engineer a solution that allows the analyzer to run our small sample," Olson commented. "We engineered a novel centrifugation process to maximize the volume available for analysis.

"In a conventional serum tube, after centrifuging the sample, the thixotropic gel creeps up and forms a protective layer between the clot at the bottom of the tube and the clean serum. That leaves the clean serum at the top, which is what we want to test. Our solution was simply to engineer the sample tube so that it is flipped upside down when centrifuged," Olson observed. "This packs the red blood cells into the specially-designed cap of the tube. Next, the thixotropic gel is packed against those cells and the serum is at the top.

"The benefit comes when we flip the tube upright," he added. "The serum settles to the bottom, and the clot and protective layer of thixotropic gel remain trapped in the cap. The result is when you take that cap off, now you've got just the clean serum.

"This totally removes the gel layer and the blood cells so that it is now possible to do primary tube aspiration and get all the way to the bottom of that tube," he said. "The lab benefits from not doing a pour off, not doing any more labeling, and not losing any sample during an aliquoting step. Plus, the risk of the probe getting clogged by gel is eliminated."

➤TOPIC FIVE:
Validation of Lab Assays Using Capillary Blood and Tested on High-Volume Analyzers

To confirm the performance of its sample collection and miniaturized analytical methods, Babson Diagnostics is conducting rigorous validation studies for the assays to show that its method of collecting and processing specimens produces results that are accurate and reproducible when run on high-volume analyzers.

"The final technical challenge is demonstrating diagnostic grade quality at every step," Olson stated. "We are doing clinical studies that include method comparisons. These involve capillary blood samples collected using this collection device at a retail pharmacy by a pharmacy tech or a pharmacist who has trained on this device. The sample goes through the automated sample preparation process.

"Each sample goes through reverse centrifugation," he said. "It gets loaded on an analyzer, and it gets tested on a miniaturized method that takes less sample volume. We track any error rate from all of those actions. The results are then compared to conventional testing.

Comparing the Differences

"That means the same individual also was drawn by a professional phlebotomist using a needle in the arm with a Vacutainer," Olson noted. "But that specimen is run through conventional sample prep, timed clotting, conventional centrifugation, and then loaded on a big analyzer using a full size, FDA-cleared method. We're comparing differences between all those things.

"These studies show excellent correlation," he added. "We share our clinical study results liberally with our partners and the people with whom we work. Many of the retail pharmacy chains that you know have seen all of these results."

Disruptive Innovations

Babson Diagnostics is an example of a new class of diagnostic company that is preparing to come to market. It is creating a novel service model for clinical laboratory testing designed to meet the changing preferences of consumers and patients.

It is interesting that, should Babson's hybrid model of decentralized sample collection married to centralized testing catch on in the marketplace, it has the potential to greatly reduce the number of phlebotomists needed by clinical laboratories to collect specimens.

This is one intriguing aspect to Babson's vision for a hybrid model of decentralized sample collection in tandem with testing done at high-volume clinical laboratories.

Across the nation, clinical laboratories are challenged to hire, train, and retain adequate numbers of phlebotomists. Thus, should Babson's new technologies obtain clearance by the **Food and Drug Administration** (FDA) to be used in clinical settings, they collectively would offer clinical laboratories a solution which reduces the reliance of labs on phlebotomists as the primary resource for specimen collection.

That could be a major benefit to both consumers and labs alike.

Strategically, clinical laboratory managers may want to track Babson Diagnostics' progress at introducing these unique blood draw and centrifugation technologies into daily patient care. TDR

Contact Eric Olson at discover@babsondx.com.

IVD Companies among Babson's Partners

BABSON DIAGNOSTICS' WORK IN DEVELOPING A CAPILLARY BLOOD COLLECTION SYSTEM has benefitted from partnerships with leading *in vitro* diagnostics (IVD) companies **Becton, Dickinson and Company** (BD) and **Siemens Healthineers**.

Since March 2017, Babson has closed on $44.6 million in Series A and B funding, which included support from investor Siemens Healthineers and other financial partners.

Meanwhile, BD and Siemens have helped with Babson's technology progress.

"We've partnered with BD for sample collection and with Siemens for sample analysis," said Eric Olson, Founder, Chairman, and Chief Operating Officer at Babson. "We have leading med tech companies in the field supporting us to bring all this technology to market. This is not a hill that a typical startup company can climb without a lot of help."

The BD Vacutainer venous blood collection device has significant market penetration in the blood draw industry. BD's participation with Babson paints a picture of an IVD company that wants to continue to have a strong foothold in the market regardless of the technology behind a blood draw.

Lab Legal Update

Lab Allegedly Billed Medicare for Tests It Did Not Perform

Following up on a Sept. 19 intelligence briefing, an attorney told The Dark Report that a federal case alleging genetic test fraud showed hallmarks of pass-through billing.

As such, it raises questions about whether reference laboratories associated with this case had obligations to report to federal authorities that they performed tests for Medicare beneficiaries, but did not bill **Medicare** for those tests, as required by law.

"Under certain circumstances, reference work might be permissible, but only if properly disclosed when billed, reported to the provider and patient, and all other relevant rules and regulations are followed," said Danielle Tangorre, JD, a partner at law firm **Robinson & Cole LLP** in Albany, N.Y.

The case involves Missouri resident Jamie McNamara, who was indicted in July on various counts of fraud and kickbacks. *(See TDR, "Feds Target Genetic Test and Telemedicine Fraud," Sept. 19, 2022.)*

McNamara operated four lab companies in Louisiana and Texas, which the government collectively called **McNamara Labs**. Federal prosecutors said that from 2018 to 2020 McNamara allegedly submitted to the Medicare program $174 million in false claims for genetic tests. McNamara did not perform the tests, instead sending the specimens to reference labs.

"The federal indictment alleges that the reference rules were not followed, and that McNamara Labs billed for the tests as if they performed them," Tangorre observed. "These appear similar to allegations in pass-through billing schemes because of allegations of failing to identify the lab performing the testing, or a failure to follow the 70/30 rule for billing, or both."

Under Medicare's 70/30 rule, if a clinical laboratory refers out more than 30% of its testing, it cannot bill Medicare for work that it refers. *(See TDR, "Attorney Explains 70/30 Rule, Pass-Through Bill Arrangements," July 9, 2018.)*

"Many pass-through billing schemes involve allegations of rural hospitals and labs using higher-paying, in-network hospital rates. Such allegations are not present in the McNamara indictment," Tangorre noted. However, the indictment mirrors concern identified in a 2020 genetic test fraud paper published by the Healthcare Fraud Prevention Partnership, in which the federal government participates.

The **U.S. Attorney's Office for the Eastern District of Louisiana** said it had no comment on the McNamara case's pass-through billing implications.

Reference Lab Relationships

It's unclear whether the reference labs involved with McNamara Labs had an obligation to report the situation, Tangorre said. Improper relationships amongst reference labs might result in similar allegations as found in the McNamara indictment.

"Any reference labs working with McNamara would have an obligation to review the nature of that relationship as it relates to all applicable regulatory rules, but we do not have enough facts here to assess their reporting obligations," she explained. "Such reference relationships might be permissible in certain circumstances."

Labs that refer genetic tests to other labs must tread carefully over the 70/30 rule, while reference labs must be mindful of the situations in which tests are sent to them. TDR

Contact Danielle Tangorre at dtangorre@rc.com.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

In yet another employment ripple from the pandemic, a group of more than 75 pathologists penned a letter to Congress urging lawmakers to retain the option for remote diagnostic work. In the letter, which appeared in the Oct. 20 issue of *Nature*, the pathologists wrote, "During the COVID-19 pandemic of the past 30 months, one of the early regulatory exemptions enabled the (optional) use of remote work in clinical laboratories and pathology." The group asked Congress to permanently amend the Clinical Laboratory Improvement Amendments of 1988 to explicitly allow pathologists to work remotely. Until then, the authors asked federal health officials to keep pandemic-related exemptions in place for remote diagnostics work.

MORE ON: *Lab Lobbying*

Pathologists have been busy in the last few months attempting to persuade members of Congress to take action that would help clinical labs and practice groups. Back in August, a group of 290 laboratory directors and pathologists, many from academic medical centers, wrote to lawmakers to voice concerns about potential new regulations that would adjust oversight of laboratory-developed tests (LDTs). THE DARK REPORT noted the influence this group wielded.

SURVEY: 25% OF CLINICIANS MAY SWITCH CAREERS

In new research that portends continued staffing shortages among anatomic pathologists, management consulting firm **Bain & Company** revealed that 25% of clinicians are considering changing careers. Bain's Frontline of Healthcare study polled 573 physicians, nurses, and advanced practice providers. The most-cited reason? Burnout. "U.S. clinicians have been bearing the brunt of a brutal environment over the past two years," Bain noted. "As clinical acuity and medical uncertainty rose with the pandemic, providers' financial health steadily slipped, and labor challenges mounted."

TRANSITIONS

- Matt Sause, President and CEO of **Roche Diagnostics** North America, will become CEO of Roche Diagnostics on Jan. 1. Aside from brief stints at **Genentech** and **Gilead Sciences** from 2018 to 2019, Sause has worked at Roche for two decades.

- **Quantum-Si** of Guilford, Conn., appointed Jeff Hawkins as CEO. Hawkins previously held executive positions at **Truvian Sciences**, **Illumina**, **GenMark**, **Hologic**, **Third Wave Technologies**, and **Abbott Laboratories**.

- **Indiana University School of Medicine** named Michael Feldman, MD, PhD, as Chair of the Department of Pathology and Laboratory Medicine effective Feb. 1. Feldman is currently Vice Chair of Clinical Services in the Department of Pathology and Laboratory Medicine at the **University of Pennsylvania Perelman School of Medicine** in Philadelphia and also teaches at the school.

That's all the insider intelligence for this report. Look for the next briefing on Monday, December 12, 2022.

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