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inSights

INTO *Lab Developed Tests*

ALSO IN THIS ISSUE:

Letter from the Chair	2
Laboratory Developed Tests: Greater Role Leads to Increased Federal Oversight.....	3
Proficiency Testing (PT): New Regulation Promotes Burden Reduction.....	8
Stories from the Front Lines	10
Laboratory Excellence Award	12
Ads	9

FROM THE CHAIR



Bradley J. Fedderly, MD,
FAAFP, Chair, COLA Board of
Directors

In this issue of COLA *Insights* we focus on the potential impact of changes in Federal legislation for two very important areas of laboratory medicine: Laboratory Developed Tests, and Proficiency Testing. This is an era of rapid technological change in the medical profession, and in the organization and administration of healthcare services.

New demands for increased oversight of in-house developed laboratory testing, which are no longer limited to simple tests developed for limited populations within the laboratory's particular patient base, have resulted in a re-assessment of the FDA's policy of "enforcement discretion". The focus of our lead article, "[Laboratory Developed Tests: Greater Role Leads to Increased Federal Oversight](#)" is about these changes.

We begin with an historical perspective of laboratory developed testing, including a discussion of why this has occurred, what has changed, and the current regulatory oversight provided by CLIA.

However, there is increased concern that this may not be enough to vet the in-house test development process. This is because these tests are now a significant part of personalized medicine (including Direct To Consumer Testing); the laboratories developing these tests apply them well outside the confines of their immediate facility; and these are now high-complexity procedures, involved with diagnoses, and critical decision making.

We then delve more deeply into the discussions and controversy surrounding the proposed increased enforcement of already existent FDA regulations for these tests.

Our second article: "[Proficiency Testing: New Rule Promotes Burden Reduction](#)" discusses the efforts by CMS to clarify the rules governing the referral of a PT sample to another laboratory, most serious violation of the proficiency testing process. The new Rule is designed to provide CMS with some flexibility when responding to these violations, depending on whether the referral was intentional, a singular event or repeated; due to misunderstanding how to handle proficiency test specimens, or was the result of an automatic process, such as reflex testing.

A new three tiered system of penalties is now in place for labs that break the rules, ranging from CLIA certificate loss, to mandated education and fines.

Thus, this issue of COLA *Insights* provides you with interesting perspectives on the changing landscape of laboratory regulation; some due to the impact of technological change; and others due to the demonstrated need to bring enforcement protocols up to date.

Bradley J. Fedderly, MD



COLA INSIGHTS

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Laboratory Developed Tests: Greater Role Leads to Increased Federal Oversight

Introduction: Historical Perspective

The 1976 Medical Device Amendments to the Federal Food, Drug and Cosmetic Act (FD&CA) gave the FDA authority to regulate medical devices, including in vitro diagnostic devices (IVDs). Defined as reagents, instruments, and systems intended for use in diagnosing disease or other conditions, IVDs are packaged products developed and distributed by medical device manufacturers and sold in interstate commerce. In regulating IVDs, the FDA focuses on their safety and efficacy, the manufacturer claims about clinical “intended use” of the devices, and the quality of the design and manufacturing process¹.

In contrast with IVD products, clinical laboratories perform and report laboratory tests for human patient diagnosis and management. They are regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), administered through the Centers for Medicare & Medicaid Services (CMS). CLIA focuses on the accuracy and reliability of the testing process, with attention to analytic quality control, proficiency testing, credentials of laboratory testing personnel, requirements for reporting results, and appropriate documentation of standard operating procedures.

CLIA allows clinical laboratories to modify FDA-approved tests, and, more importantly, to develop their own tests—laboratory-developed tests (LDTs)—as long as they follow the requirements to validate the performance characteristics of the LDTs.

This is demonstrated by CLIA requirements that laboratories demonstrate how well an LDT test performs using certain performance standards, including:

- **Accuracy**- the ability of a test to most closely measure the “true” value of a substance
- **Precision**- the reproducibility of a test result
- **Test sensitivity**- the ability of a test to detect a substance especially at relatively low levels
- **Test specificity**- the test’s ability to correctly detect or measure only the substance of interest and exclude other substances²

Routine, regular inspections under the auspices of CLIA are intended to ensure that these necessary steps are being followed for the LDTs offered for patient care purposes.

In the past, laboratory developed tests have also been referred to as “in-house” tests. Often, a laboratory will choose to develop and use an LDT because a commercial test is not available. LDTs generally have not been subjected to FDA oversight because these diagnostic tests are never sold to other laboratories or hospitals. Historically, LDTs comprised a relatively small volume of tests that were relatively simple, intended for use in diagnosing rare diseases or to meet the needs of a local patient population. However, unlike traditional LDTs, modern LDTs are more complex; widely used to screen for common high-risk diseases, such as breast cancer and Alzheimer’s disease, rather than rare diseases; manufactured in high volume by large corporations with international reach and offered beyond local patient populations; manufactured with components that are not legally marketed for clinical use; and present higher risks that are similar to those of other IVDs that have undergone premarket review (e.g., used in guiding critical treatment decisions).

In light of these profound shifts in the technology and business practices with respect to the use of LDTs, the FDA currently believes that its policy of general enforcement discretion towards LDTs may no longer be appropriate. As a result, the FDA has begun to revisit its role in the regulation of LDTs. There appear to be two main factors which have caused increased concern on the part of the FDA: the use of LDTs in the exponentially growing field of molecular diagnostics, which includes tests that are used to assess high-risk conditions and supply information for critical decision-making; and the increasing number of LDTs being manufactured by corporations with far-reaching markets rather than hospitals serving local populations. These commercial companies, many with their own CLIA-certified laboratories, offer direct-to-consumer (DTC) genetic testing. The FDA has become increasingly concerned about the use of improperly clinically validated tests that may pose a public health risk. The FDA has also expressed concern that the current lab accrediting agencies are focused on test

>> CONTINUED ON PAGE 4

LABORATORY DEVELOPED TESTS: GREATER ROLE LEADS TO INCREASED FEDERAL OVERSIGHT

analytical validity, and not the clinical validity and use of the tests, making FDA oversight necessary³.

There can be several reasons why a commercial test has not been developed for a particular analyte or disease of interest. For example, many LDTs are genetic tests developed for rare diseases. These are also diseases affecting only small subset of the population, thus reducing the incentive for a manufacturer to develop a commercial version because the market for such a product would be small, without a potential decent return on investment. Or, an existing test may not apply to a particular subpopulation from which the lab has patients, so modification of the test is required. (Any FDA-approved commercial test that is modified in any way by a lab is considered to be a laboratory-developed test and is subject to the regulations applied to all lab-developed tests.)⁴

The Current Landscape

Estimates suggest that thousands of diagnostic tests, including the majority of genetic tests, are currently offered as LDTs. The list of testing which is currently being performed almost exclusively by LDTs includes newborn screening; diagnosis of genetic defects, including metabolic disorders; infectious disease testing, especially viral load testing for diseases such as HIV, CMV, EBV, and respiratory viruses; immune-histochemical stains for the diagnosis of cancers; tandem mass spectrometry, testing for a wide variety of analytes ranging from thyroid tests to immunosuppressant drugs to vitamin D; next generation gene sequencing; comparative genomic hybridization array testing; genetic variants of the Cytochrome P450 drug metabolism system and determination of appropriate individual drug dosing; and drug screening and confirmation assays, to name a few.⁵

Direct To Consumer Testing

Commercial companies, many with their own CLIA-certified laboratories, now offer direct-to-consumer (DTC) genetic tests. Such tests give consumers information about their own genetic markers, from physical traits (such as baldness) to certain disease associations (such as prostate cancer). The identification of these “genome-wide disease associations” has become increasingly popular among consumers.

Although, many of these disease associations are weak to moderate at best, there is a growing list of companies offering this kind of information on an increasing number of conditions. The important distinction that needs to be made is that these tests offer “prediction” through statistical possibilities. They do not provide statistical certainties—a critical point that can easily be lost in translation in the marketing and consumer use of such products. Furthermore, *prediction* does not equal *diagnosis*. Because there are frequently so many other genetic and environmental factors that can determine whether a disease actually emerges, it is critical that consumers fully understand that the risk may never become reality. Similarly, the absence of a genetic risk factor (or the presence of a favorable one) may still not prevent subsequent development of disease. This context about the known association between a disease and genetic markers must be clearly communicated to the consumer through counseling—done best by medical professionals, particularly professionals trained in medical genetics.⁶

The fact that many of these DTC companies develop their own tests and testing platforms has led the FDA, as well as members of Congress, to believe that these LDTs are medical devices that must be carefully regulated so that the analytic and clinical validity and clinical usefulness are clearly understood, to protect the public safety. Accordingly, additional regulatory safeguards, provided by FDA IVD oversight to ensure the accuracy of LDTs, particularly high-risk LDTs, are under consideration to better ensure that patients do not seek unnecessary treatments, delay needed treatments or become exposed to inappropriate therapies.

Controversy regarding how FDA regulations can be applied to LDTs⁷

At the same time, the decision about whether, and how, to regulate LDTs remains far from unanimous. Below are some of the pro and con statements of professional associations and ad hoc groups:

ASCP

The American Society for Clinical Pathology published a Policy Statement regarding regulation of laboratory developed tests:

“Accrediting bodies should continue to monitor the performance and quality of LDTs, but that role should be post-clearance, to avoid any conflicts of interest”. It advocated for the establishment of an independent, third party reviewer to verify quality and accuracy of claims prior to review by FDA, and the federal CLIA-regulating agencies that would enhance the transparency of the process. The criteria established by the FDA should be risk-based, and while high risk LDTs should fall under the purview of the FDA, lower risk LDTs, those not deemed to be “in vitro diagnostic multivariate assays” should continue to be regulated by CLIA. Implementation should be in a step-wise fashion, and could first require compliance for high-risk tests, and later implement requirements for moderate and low-risk tests. Finally, evaluation of LDTs, as with any other diagnostic laboratory test, should include the test’s analytic and clinical validity.⁸

AACC⁹

“Some members of Congress have been floating a proposal to increase regulatory oversight of LDTs, suggesting that Congress create a new agency within FDA to oversee all lab tests, including LDTs.

Some aspects of this proposal make sense—such as getting labs to demonstrate the accuracy of LDTs, and exempting critical tests, such as those for public health emergencies and newborn screening, from increased regulatory scrutiny, [AACC wrote](#) in a letter to Congress.

However, the association is concerned that dual scrutiny from both CMS and FDA would impede patient access to testing, since many hospitals and rural testing facilities do not have the resources to comply with FDA’s requirements and would be forced to stop performing laboratory developed tests,” AACC’s letter stated.

Instead, Congress should work within CMS’s regulatory framework to tighten scrutiny of LDTs. Rather than have FDA assume the task of assessing the clinical validity of LDTs, handing that responsibility to CMS would “be a relatively minor adjustment considering many CMS-accredited laboratories are already required by private accrediting bodies to demonstrate clinical validity,” the letter said.

ACLA¹⁰

The American Clinical Laboratory Association has repeatedly argued that LDTs already face stringent oversight under a federal law that requires monitoring of the reliability of the tests.

“FDA regulation of LDTs would be contrary to the public health. Numerous critical tests are only available as LDTs, including many “gold standard” DNA sequencing assays, newborn screening tests, and tests for rare diseases. If FDA were to require clearance or approval for LDTs, laboratories may be unable to continue offering them. Some testing currently performed at laboratories as LDTs will never generate the financial returns to justify the costs of obtaining FDA clearance or approval. Patients served by these tests would be left with no testing options. Similarly, critical testing would be unavailable in the “lag time” between development of new tests and FDA authorizing them, and subsequent improvements on existing tests would slow significantly under the rigid, inflexible, and duplicative FDA regulatory scheme.”

AboutLawSuits.com¹¹

Previously, the agency (FDA) has taken a hands-off approach to the studies, because they were simple, confined to local labs, and often used to diagnose rare conditions, Dr. Peter Lurie, Associate Commissioner for Public Health Strategy and Analysis, said in an FDA Voice blog on November 16 (2015) “LDTs have increased in complexity and availability and are now frequently used to diagnose common, serious medical conditions, including cancer and heart disease, with potentially greater impact on patients. And yet, LDTs are still under a general policy of enforcement discretion,” Lurie wrote. “That means they have rarely undergone FDA review to determine whether they are accurate, reliable, and provide clinically meaningful results. It also means that FDA’s own adverse event reporting databases rarely capture problems associated with a faulty LDT.” In addition to a lack of adverse event reporting, the FDA report found that there is no premarket review of LDTs, manufacturers often make unsupported claims about their effectiveness, there is inadequate product labeling, a lack of transparency, and that other laboratories that have to go through official vetting processes are at an unfair disadvantage to LDTs. The

>> CONTINUED ON PAGE 6

LABORATORY DEVELOPED TESTS: GREATER ROLE LEADS TO INCREASED FEDERAL OVERSIGHT

agency's report also noted that LDTs could be a threat to the scientific integrity of clinical trials when researchers rely on their results.

Others:

Nearly two dozen **university lab directors from around the country** expressed opposition in a recent letter to the Office of Management and Budget (OMB), arguing that LDTs are not technically medical devices and that allowing the FDA to regulate them would slow the development of critical testing and ultimately do a disservice to patients. The OMB must approve regulations proposed by federal agencies.

"The ability of laboratories to develop custom diagnostic tests has been critical to the growth of personalized medicine and keeping pace with the changing face of disease to best serve patients and clinicians," they wrote. "FDA regulation of laboratory developed tests would stifle the medical innovation occurring in academic medical centers today, and interfere with our ability to care for patients."¹²

CLIA¹³

When a laboratory develops a test system such as an LDT in-house without receiving FDA clearance or approval, CLIA prohibits the release of any test results prior to the laboratory establishing certain performance characteristics relating to analytical validity for the use of that test system in the laboratory's own environment. This analytical validation is limited, however, to the specific conditions, staff, equipment and patient population of the particular laboratory, so the findings of these laboratory-specific analytical validation are not meaningful outside of the laboratory that did the analysis. Furthermore, the laboratory's analytical validation of LDTs is reviewed during its routine biennial survey – after the laboratory has already started testing.

In contrast, the FDA's review of analytical validity is done prior to the marketing of the test system, and therefore, prior to the use of the test system on patient specimens in the clinical diagnosis/treatment context. Moreover, the FDA's premarket clearance and approval processes assess the analytical validity of a test system in greater depth and scope. The FDA's processes also assess clinical validity,

which is the accuracy with which the test identifies, measures, or predicts the presence or absence of a clinical condition or predisposition in a patient, as part of the review that is focused on the safety and effectiveness of the test system.

Furthermore, unlike the FDA regulatory scheme, CMS' CLIA program does not address the clinical validity of any test.

Thus, the two agencies' regulatory schemes are different in focus, scope and purpose, but they are intended to be complementary.

FDA

The FDA has identified problems with several high-risk LDTs including: claims that are not adequately supported with evidence; lack of appropriate controls yielding erroneous results; and falsification of data. The FDA is concerned that people could initiate unnecessary treatment or delay or forego treatment altogether for a health condition, which could result in illness or death. The FDA is aware of faulty LDTs that could have led to: patients being over- or undertreated for heart disease; cancer patients being exposed to inappropriate therapies or not getting effective therapies; incorrect diagnosis of autism; unnecessary antibiotic treatments; and exposure to unnecessary, harmful treatments for certain diseases such as Lyme disease.

To help health care providers and patients better rely on the thousands of laboratory tests that are used every day to diagnose disease or other conditions or guide treatment and to encourage the advance of personalized medicine, on July 31, 2014 the FDA notified Congress of the Agency's intent to issue a draft oversight framework for LDTs based on risk to patients rather than whether they were made by a conventional manufacturer or a single laboratory. This draft oversight framework includes pre-market review for higher-risk LDTs, like those used to guide treatment decisions, including the many companion diagnostics that have entered the market as LDTs. In addition, under the draft framework, the FDA would continue to exercise enforcement discretion for low-risk LDTs and LDTs for rare diseases, among others. The framework would be phased in over many years.¹⁴

Summary

Laboratory developed tests or LDTs are increasingly being integrated into standard practice for diagnosing and managing disease, predicting the risk of developing disease, and informing decisions about lifestyle and behavior. These tests are enabling improved prevention, treatment, and disease management for an array of common chronic conditions such as cancer, heart disease, and diabetes, as well as rare genetic disorders. They have become indispensable tools in the practice of medicine.

Since 1988, the laboratories performing LDTs have been highly regulated by a comprehensive federal statutory framework under the Clinical Laboratory Improvement Amendments (CLIA), which requires continuous monitoring to ensure validity and reliability of LDTs. For the last few years, however, the Food and Drug Administration (FDA) has expressed its intent to regulate LDTs as medical devices.

While concerns about the effect of more oversight and regulation by the FDA on the development of new LDTs have been expressed by numerous laboratory professionals and organizations, all indications point to implementation of the new FDA guidances.

The FDA will focus its initial efforts on reviewing LDTs that have the same intended use as an FDA-approved or -cleared companion diagnostic or class III medical device, as well as LDTs that determine the safety or efficacy of blood or blood products. The FDA intends to continue to exercise enforcement discretion with respect to quality system regulation requirements until a manufacturer of a given LDT submits a Pre-market Approval or the FDA issues a 510(k) clearance order for the LDT.

Implementing the FDA's proposed guidelines on regulating moderate- and high-risk LDTs is likely to have a profound impact on the market for personalized medicine. Around 11,000 tests developed by 2000 different laboratories are predicted to fall under FDA's proposed framework. Thus, it is becoming increasingly evident that providers of moderate-risk and high-risk LDTs that were once largely shielded from FDA oversight will now have to seek FDA approval or clearance.¹⁵

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Proficiency Testing (PT): New Regulation Promotes Burden Reduction

Introduction

On May 12, 2014 The Centers for Medicare and Medicaid Services (CMS) published the “Final Rule - Promoting Program Efficiency, Transparency, and Burden Reduction; Part II.” This implements reforms that CMS identified as unnecessary, obsolete, or excessively burdensome on health care providers and beneficiaries, as well as certain regulations under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).¹

This rule includes adjustments to regulations governing actions taken when the most serious violation of proficiency testing requirements is discovered: that of referring a PT sample to another laboratory. Under recent regulations, any laboratory that intentionally referred a PT sample to another laboratory for analysis automatically lost its CLIA certificate for at least one year. CMS has always interpreted the term “intentional” very broadly to mean an intention to act and thus has not considered the circumstances surrounding the referral of a PT sample when imposing revocation.²

This new regulation from CMS does a better job of explaining exactly what labs can and cannot do with PT samples. This reflects the inclusion of the recently enacted Taking Essential Steps for Testing Act of 2012 (TEST Act), which gives CMS the express authority to impose alternative sanctions in the event of a PT referral. Specifically, the word “will” would be replaced with “may” in the regulation that currently requires revocation of a laboratory’s CLIA certificate if it refers a PT sample to another laboratory.

The regulation defines a three-tiered system of penalties for those that break the rules—all the way from mandated education and fines, to shutting down labs.

Three Levels of Penalties³

The first category of offense encompasses cases of repeat PT referral or cases in which a laboratory intentionally reports another laboratory’s test results as its own—deliberate cheating.

In these instances, CMS has the authority to revoke the lab’s

CLIA certificate for at least 1 year, ban the owner and operator from owning or operating a CLIA-certified laboratory for at least 1 year, and potentially impose a civil monetary penalty.

CMS allows itself a certain amount of discretion when the owner of the lab is a large health system that operates several laboratories. In such a case, a full owner ban could shut down a large number of laboratories in one community, threatening patient care. In the new regulation, CMS added a provision to limit the reach of the owner ban for laboratories under the same ownership as the revoked laboratory, but only if there is no evidence that the other labs participated or were complicit in the PT referral.

The second category of sanctions apply when a lab refers PT samples to another lab—defined as a lab that operates under a different CLIA number—before the PT event close date, but still reports its own results to the PT program.

In this case, CMS could suspend or limit the CLIA certificate for less than 1 year rather than revoke the CLIA certificate, and include other alternative sanctions, such as training for the lab’s staff.

For the third, least serious category, CMS has the option to use only alternative sanctions, including a civil monetary penalty and CMS-directed staff training.

This category covers a variety of cases in which a lab may unintentionally refer a PT sample to another lab, but catches the error, reports its own results, and importantly, never receives any results back from the second lab. CMS notes this can happen if a reference lab courier mistakenly picks up PT samples along with patient samples.

In the final rule CMS clarified that a referral would not be considered “intentional” if a CMS investigation revealed that PT samples were sent to another laboratory for reflex, distributive, or confirmatory testing; the referral was not a repeat offense; and the referral “occurred while acting in full conformance with the laboratory’s written, legally accurate, and adequate standard operating procedure.” In effect, this rule clarifies that the laboratory should treat the PT sample

like a patient sample up until the point it would refer the patient sample to a second laboratory for further testing; that referral is not acceptable, even if that is the protocol for patient specimens.

An Ounce of Prevention...

Probably the easiest way to avoid accidentally referring a PT sample to another lab involves creating special mock patients in the laboratory information system (LIS). The lab can flag the mock patient records, noting they should never be sent out. This enables the PT sample to make its way through the lab just like an ordinary patient specimen—one of the cornerstones of PT—but not end up leaving the lab, explained Gary Horowitz, MD, the director of clinical chemistry at Beth Israel Deaconess Medical Center in Boston and associate professor of Pathology at Harvard Medical School.

“We put them in as patients because that ensures they’re handled like patients, but you have to have the flag that says ‘don’t refer,’” Horowitz said. “This system works very well for us. It’s very clean and simple. And to the bench technologist, it’s just another patient.” Having such a system in place is especially important with reflex testing rules, which are

becoming more common as a quality assurance strategy, Horowitz said.⁴

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Stories from the Front Lines: Helping Make the Diagnosis

Name: Linda Papik, BA, MT (ASCP)
Title: Laboratory Manager
Employer: Arthritis Center of Nebraska Laboratory

Our practice is dedicated to helping people with rheumatoid arthritis (RA), osteoporosis, autoimmune diseases and other musculoskeletal conditions. We perform over 150,000 lab tests annually in Chemistry, Urinalysis, Hematology and Immunology. Even though we're not specialized in areas like Hematology or Oncology, our lab recently made an impact in a patient's early diagnosis of Chronic MyeloMonocytic Leukemia (CCML).

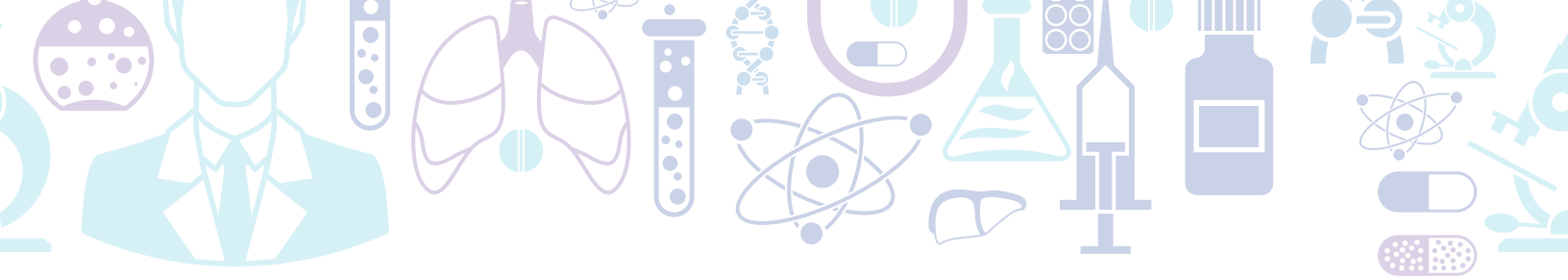
Back in 2010, this patient, a 65-year old male, had had a bone marrow performed. He had a history of "paraproteinemia," an excess of proteins in the blood, a condition which can either be benign or associated with multiple myeloma. His was considered "silent" or benign.

When he was diagnosed with RA in 2013, we began conducting Complete Blood Count tests on him. From 2013 through 2014, his white blood cell count (WBC) ranged from 5.3 to 7.5, with no abnormalities noted. A follow up visit to his oncologist in February, 2015 also showed no abnormal WBC,

with his diagnosis still remaining RA and silent paraproteinemia.

But beginning this past May, we began to see evidence of his WBC shooting up, first to 18.9, then to 26.0 in July, then back to 20.9 in August. When it hit 26.0, triggering a manual differential test, the technologist observed that there were very slight variations in the normal numbers of the different types of white and red blood cells and macro platelets. The tech consulted with the Lab Manager, and they decided to send the slide to our Pathologist for a consult. At this point, it seemed to all the techs that had been performing his CBCs and other tests over the years that his WBC was becoming more elevated with the passage of time, and that the percentages of the different cells on his differential were becoming more abnormal – even though these changes were very slight.

Several days later, we received the pathologist's report, which indicated that some myeloid malignancies were present in addition to some rare



blast cells. Further testing resulted in the CCML diagnosis in August, and treatment was immediately started. I believe our lab team’s vigilance – particularly given the very slight differences they were noticing in the percentages of his cells — made all the difference in getting this patient the treatment he needed, when he needed it most.

Visit [LabTestingMatters.org](https://www.LabTestingMatters.org) to read more Stories from the Front Line of the Lab and join us as we build a community to support quality laboratory medicine. If you are interested in sharing your story with the Lab Testing Matters Community you can contact Victoria Farrell at vfarrell@cola.org or submit your story online.

inSights SPOTLIGHT: LABORATORY EXCELLENCE AWARD



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Summit Medical Group is one of the largest primary healthcare organizations in the U.S., with over 1 million patient encounters annually. Summit provides integrated care and services at over 90 locations and six hospitals in 12 counties with 211 physicians and 129 Advanced Practitioners (NPs and PAs). Summit physicians include primary care, internal medicine, sleep specialists, rheumatology, pulmonary, occupational health and hospitalists. Additionally, Summit maintains three Summit Express Care (SEC) centers; one of the largest hospitalist programs in the nation; an 8-bed, fully accredited Sleep Center facility; and eight

Physical Therapy locations. Summit is recognized nationally for quality medical management and innovation and is certified by the National Commission on Quality Assurance (NCQA) for clinical excellence in heart/stroke and diabetes care. Additionally, Summit is recognized as the nation's largest NCQA-certified Patient-Centered Medical Home (PCMH).

Summit is a leader in the provision of ancillary care and diagnostics, including laboratory and imaging services. Summit maintains 4 imaging centers and mobile imaging services to provide improved patient access to diagnostic testing. Summit Central Laboratory, operates on the scale of a large reference lab and performs in excess of five million tests per year.

The Summit Central Lab provides a comprehensive source of diagnostic services. Summit Central Lab operates under the direction of a board certified pathologist and is staffed by 24 highly trained, certified laboratory professionals and support staff. The quality of all testing is insured by the strictest standards and protocols. The facility is accredited by COLA, which also named Summit a Laboratory of Excellence.

The Summit Central Laboratory operates at high efficiency, processing over 22000 test orders in two shifts Monday through Friday. More than 96% of all Summit laboratory tests are performed at the Summit Central Lab, including general chemistry, immunochemistry, hematology, coagulation, and urinalysis. Summit's Central Lab continually evaluates testing and equipment needs to provide our patients the very best in diagnostic laboratory testing, including the addition of infectious disease for 2016.

Integration of the Lab's LIS system with Summit's electronic medical records system provides greater continuity of care, efficiency and cost effectiveness among clinicians and facilities. Patient results are available in real time to all Summit physicians within less than 24 hours of specimen receipt. Additionally, the LIS provides integration with reference labs for secure ordering and results receipt. The Central lab manages the outsourcing of esoteric tests to external reference lab partners. Summit Central Lab also provides oversight of Summit in-office testing, CLIA certification, lab compliance, and phlebotomy.