



COLA[®]

ISO 9001:2008

Accreditation Education Innovation

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COLA at a Glance

- WHO WE ARE:** COLA is a physician-directed organization whose purpose is to promote excellence in laboratory medicine and patient care through a program of voluntary education, consultation, and accreditation.
- WHY WE EXIST:** COLA was founded in 1988 as a private alternative to help laboratories stay in compliance with the new Clinical Laboratory Improvement Amendments (CLIA). In 1993, the Health Care Financing Administration (now CMS) granted COLA deeming authority under CLIA, and in 1997 the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) also recognized COLA's laboratory accreditation program.
- WHO WE SERVE:** COLA serves almost 8,000 medical laboratories nationwide, making it the largest private accreditor.
- WHAT WE OFFER:** COLA's goal is to improve patient safety by promoting laboratory excellence. By serving as an educator and a partner to laboratories, we make the accreditation process simple, quick, and tailored to meet specific needs. More importantly, the holistic approach we take makes us a daily force for quality in the laboratories we serve – not just once every two years.
- HOW WE INNOVATE:** COLA offers a **broad selection of educational products, services, and informational tools** – including webinars, biannual symposia, publications, web tools like COLAinsider.com, and ready access to expert opinion – not available elsewhere.
- Our **technological tools** – like **COLAcentral**, where laboratory professionals can update their lab profile, view communications, see survey results, prepare for upcoming surveys and receive support for a whole range of laboratory needs, and **Eval**, which allows COLA surveyors to provide paperless, preliminary results on the spot – deliver value to our clients.
- COLA is also willing to subject itself to the same kind of third party review our surveyors perform for our customers. COLA is registered under **ISO Standard 9001: 2008** – the only healthcare accreditation organization deemed by CMS to be so certified.

COLA Members



Board of Directors

AAFP Appointees

Keith E. Davis, M.D.

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COLA CEO



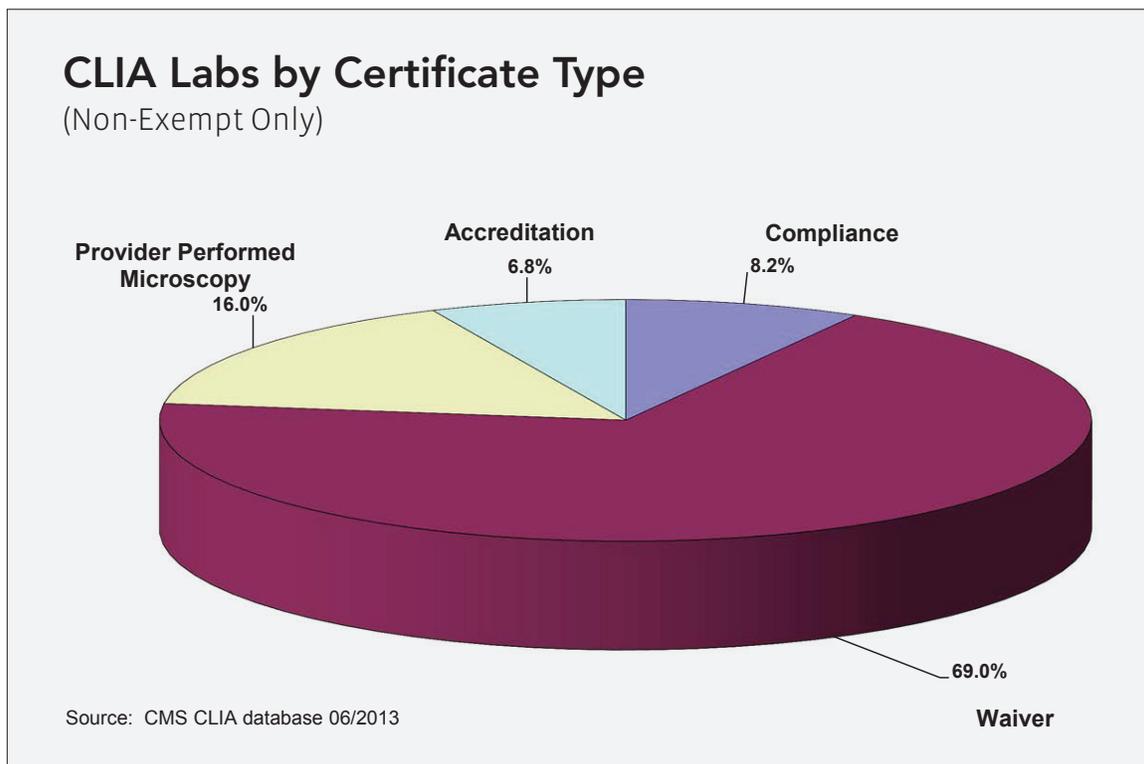
DOUGLAS A. BEIGEL, CHIEF EXECUTIVE OFFICER, COLA

Promoted to CEO after serving as Chief Operating Officer of COLA since 1987, Mr. Beigel leads a dynamic team responsible for helping nearly 8,000 laboratories across the country fulfill their accreditation obligations under the federal Clinical Laboratory Improvement Amendments (CLIA) of 1988, a complex process involving multiple layers of government. COLA staff has performed more than 70,000 surveys since 1988.

Under Mr. Beigel's leadership, COLA has become a recognized thought leader in the field of laboratory medicine, introducing a number of industry "firsts," such as:

- Developing the first-ever Quality Management System (QMS) for laboratory accreditation in the United States.
- Becoming the first CMS-deemed accreditor to achieve and maintain certification under ISO's rigorous 9001:2008 standard affecting "quality management systems."
- Devising a universal accreditation model that can be adapted by any organization in any field to review the implementation of quality standards, while preserving opportunities to make process improvements.
- Applying a holistic approach to accreditation, stressing education, consultation, and technological innovation. COLA provides laboratories with the guidance to navigate a complex accreditation process, while providing the information, expert advice, classroom opportunities, and emerging best practices in the area of quality control.
- Creating a groundbreaking laboratory management desktop tool (www.colacentral.com) that gives laboratory personnel the ability to manage regulatory compliance requirements electronically.

Clinical Laboratories at a Glance



DID YOU KNOW?

In 1988 there were fewer than 8 waived tests. Today there are over 300. ~ CMS

In 1988 78,825 labs held a certificate of waiver. Today there are nearly 154,000. ~ CMS

More than 40,000 current lab jobs are vacant in the United States. ~ Bureau of Labor Statistics.

The number of clinical lab workers is set to rise about 16 percent between 2008 and 2018, adding about 25,000 jobs. ~ U. S. Labor Department statistics

85 percent of all laboratory testing (waived testing plus PPM) is unregulated.

How COLA's Accreditation Process Works



STEP 1 - ENROLLMENT

- Laboratory joins COLA and receives information packet and manual.
- Laboratory informs their proficiency testing provider to release results to COLA for ongoing monitoring.
- Laboratory receives full access to all of COLA's signature educational tools and services, including COLAcentral, a desktop managing tool.
- Laboratory submits demographic information to COLA (CLIA #, Personnel, Tests and Test Menu, Instruments, Annual Test Volume, etc.)

STEP 2 - SELF-ASSESSMENT

- Laboratory conducts Self-Assessment and submits the information to COLA.
- Laboratory makes improvements needed to comply with all COLA criteria.

STEP 3 - ON-SITE SURVEY

- COLA surveyor performs on-site survey.
- COLA surveyor shares preliminary survey findings and provides educational guidance.

STEP 4 - POST-SURVEY & CORRECTIVE ACTION

- COLA carefully analyzes site data and issues formal post-survey report.
- If noncompliant criteria are identified:
 - COLA makes educational materials available to the lab at no cost.
 - COLA's technical staff provides hands-on consultation, support and advice.
- Lab develops and acts upon corrective plan, providing COLA with appropriate documentation.

STEP 5 - ACCREDITATION

- Laboratory receives COLA Accreditation Certificate (valid for two years).
- COLA follows lab performance on a continuing basis, including monitoring proficiency testing.
- Laboratory can use COLAcentral to help them stay in daily (rather than biennial) compliance with CLIA and COLA quality requirements and all appropriate state licensure standards.
- COLA's Quality Advisors help laboratories work to achieve a zero citation culture in between biennial surveys.





Why ISO Certification Matters

COLA IS THE FIRST AND ONLY CMS-DEEMED ACCREDITOR TO ACHIEVE COVETED DESIGNATION

COLA surveys nearly 8,000 clinical labs across the country, helping them meet if not exceed CLIA standards through its industry-leading program of voluntary education, consultation, and accreditation.

But the only way to be the best is to have it independently verified. That's why COLA's board opened the organization up to the same type of rigorous, third-party review it routinely delivers to clients.

COLA pursued and received certification under ISO's 9001:2008 standard affecting quality management systems. COLA's certification covers all delivery and administration activities for its accreditation program.

Winning ISO required COLA to embrace a significant change in culture, and to rededicate itself to its mission at a fundamental level. Team members learned to look for mistakes and embrace the opportunity to fix them. As a result, they improved COLA's ability to deliver value to clients.

In preparation for the audit, all COLA's activities – customer interaction, system innovation, technical training – were scrutinized. While remaining CLIA compliant, COLA's policies and procedures were aligned with more stringent ISO standards affecting quality management systems.

After the auditor arrived, the process included over 20 hours of the auditor observing how COLA's team members perform their work. From observing a surveyor in action to watching technical advisors reviewing paperwork and scheduling laboratories for on-site surveys, every key process was thoroughly reviewed.

By achieving ISO certification, COLA demonstrates that it is the best of the best among accreditors. It enhances its ability to protect patient safety by promoting lab excellence. And it demonstrates a commitment to the kind of continuous approach to quality assurance it advocates to the labs it serves.

The International Organization for Standardization (ISO) has developed over 18,500 International Standards on a variety of subjects and some 1,100 new ISO standards are published every year.





COLA Case Study: One Lab's Turn-Around Story

COLA is helping laboratories move away from a mindset focused on biennial surveys, and towards one which emphasizes making quality a daily, living concern. To that end, COLA's new subsidiary, COLA Resources, Inc.[®], and its two COLA Quality Advisors recently played a big role in a lab turnaround.

A small physician's office laboratory, located in the north eastern region of the US, had been in operation for approximately eight months, performing toxicology testing. CRI[®] was contacted by the laboratory, requesting an objective audit be performed to ensure all laboratory policies and procedures adhered to regulatory requirements, for an upcoming accreditation survey. An onsite audit scheduled and was performed by one of CRI's CQAs. During the on-site audit, it was discovered there were no Policy and Procedure Manuals in place; Competency Testing for laboratory personnel was not implemented, and the laboratory staff assumed all testing performed in their laboratory was moderately complex.

Due to the audit performed by the CQA, the laboratory was able to take immediate steps to ensure they could continue to operate by hiring new qualified personnel, and they began developing and implementing general Laboratory Policy and Procedure manuals.

FINDINGS: all testing performed in their laboratory was high complexity, not moderate complexity. As a result, neither laboratory personnel nor the lab director was qualified to perform the testing. If the laboratory director wanted to continue testing in his laboratory, he faced two options: purchase a new instrument (moderate complexity), or hire new personnel (for high complexity).

Due to the audit performed by the CQA, the laboratory was able to take immediate steps to ensure they could continue to operate by hiring new qualified personnel, and they began developing and implementing general Laboratory Policy and Procedure manuals. The laboratory is now in a position to become regulatory compliant, having qualified personnel perform the testing, with periodic competency assessment performed. Outcome: the laboratory will provide improved patient care through improved level of quality service.





Accreditation Education Innovation

COLA's Surveyors: The Best of the Best

When it comes to protecting patient safety and promoting laboratory excellence, COLA works hard to be the best. But being the best means a willingness to recruit and retain the very best team. That commitment to excellence in hiring is especially evident among the members of COLA's surveyor team - men and women who serve as lab quality ambassadors to COLA clients across North America.

COLA's surveyors know their way around a lab bench. That's because they are laboratory veterans themselves. Each is a certified medical technologist with at least six years' lab experience earned before they even came to COLA. Each also holds at least a bachelor's degree in a relevant scientific discipline. Each understands the laboratory culture, and the importance of adhering to best practices and processes in order to ensure quality is achieved not just every two years, but every day.

Further, COLA surveyors are trained to minimize the role of subjectivity in the surveying process. Through the principle of "inter-rater reliability," COLA ensures that surveyors sent into the same lab on different occasions will each recognize the same quality issues when they see them.

When it comes to performing their duties, COLA's surveyors operate strictly by the book. But when they identify an area in which a lab is non-compliant with CLIA or state licensure standards, they and other members of COLA's technical team will work constructively with the labs' staff to help find a permanent solution. They function as necessary if sometimes critical partners, not adversaries.

And, COLA continues to leverage technology to enhance surveyors' ability to deliver value to customers. For example, COLA's paperless "Eval" system helps surveyors perform their duties in a faster, more efficient, environmentally friendly manner, allowing them to give clients preliminary, on-the-spot survey results.

COLA's 26 surveyors serve more than 7,000 labs across the United States as well as in Canada, Bermuda, and Virgin Islands. One of COLA's surveyors performed 300 surveys in a single year.



COLA's Culture of Innovation

Pushing the technological envelope is one of COLA's hallmarks. Whether giving surveyors the capability to give clients immediate results, or enabling lab professionals to manage regulatory compliance requirements electronically, we understand that embracing new technologies and ever better ways of doing business sharpens our ability to deliver value to clients.

LINQ: COLA's proprietary database tool allows it to stay connected with every lab it serves. It gives COLA's staff immediate access to facts about the lab's history, its staff, its CLIA certificate status, and other critical information.

COLAcentral: COLA's online portal helps labs remain in daily rather than biennial compliance with lab quality standards. It gives clients the tools and education needed to prevent repeat citations, keep staff compliant with CLIA, COLA, and applicable state standards, store documents, and perform other critical management tasks. It also enhances communications by allowing users to upload documents directly to COLA and view communications sent to the lab.

COLA's newest learning tool is designed to help physician office and hospital laboratories perform cost/benefit analyses on a wide array of lab tests. LabClarity enables lab managers to evaluate differing scenarios such as procedure methodologies, personnel utilization, and reimbursement fees, to better understand the cost effects of testing, thereby improving operational efficiency.

VIRTUAL OFFICE ENVIRONMENT: COLA empowers clients and stakeholders alike through a seamless, convenient, user-friendly, virtual communications system which makes it just as easy to reach people in the field as it does at COLA's headquarters. Simply put, people who call COLA have an easier time connecting quickly with the person they need because of its new, state-of-the-art system.

EVAL: COLA's new proprietary survey system is paperless and doesn't require a live Internet connection. The data can now be recorded in the field and easily uploaded later. And, it allows surveyors to give labs preliminary, on-the-spot results after the survey is complete. Surveyors therefore are able to refocus time once spent on data entry on educating lab staff in the field.

ONLINE LEARNING: COLA webinars addressing timely and relevant topics are presented six times a year. On average, 90-98% of participants say they would recommend the COLA webinar program to others. And COLA's Lab University program is undergoing a dramatic expansion. Seventy revised courses will be delivered on the best program available, ensuring clients have the best online learning experience possible.

By leveraging existing technologies as well as designing its own proprietary solutions to benefit its clients, COLA continues to be the best of the best among accrediting organizations.

COLAcentral's flexible platform, maintained by dedicated support staff, provides COLA opportunities to add other value-added features, such as a new competency assessment tool for lab staff.





Accreditation Education Innovation

COLA: Making Lab Quality a Living Concern

The Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) is the federal law intended to ensure the accuracy, reliability, and timeliness of patient test results. To maintain their CLIA certification, labs which perform anything more complex than waived testing or provider-performed microscopy must be surveyed every two years by either CMS or a private accrediting organization like COLA. Additionally, California and several other states require surveys as part of their own licensure requirements.

Biennial surveying presents a snapshot of quality at any given lab. The real challenge is to help laboratorians integrate quality policies and procedures into their daily lives. That's why COLA is helping its clients move beyond the snapshot and towards a mindset emphasizing daily, continuous compliance with COLA's own rigorous quality guidelines.

COLA offers the following tools and services to help clients make quality a permanent part of the lab culture.

To assist laboratories in framing their proper role in emerging new healthcare delivery models, COLA recently introduced a new recognition program, called Patient Centered Laboratory Excellence (PCLE) which emphasizes good laboratory practices above and beyond current regulatory requirements for all laboratories regardless of their CLIA-designated complexity. Practitioners using the services of a COLA PCLE-recognized laboratory can be assured of high quality results, generated by well trained staff who use state-of-the-art communications to deliver enhanced access to results to both patients and providers.

- **TECHNOLOGY:** COLAcentral, COLA's online portal, gives clients everyday access to the resources needed to prevent repeat citations, keep staff compliant with CLIA, COLA, and applicable state standards, test staff competency, store documents, and perform other critical management tasks.
- **CONSULTATION:** COLA's professionals are available to its clients through monthly and individual training sessions, yearly in person gatherings, webinars and LabUniversity classes. COLA's two Quality Advisors, who help make quality a daily living concern in the laboratories they serve, are only a phone call away.

Patients do not think of quality in snapshot terms. Neither does COLA. By helping its clients treat quality as a continuous, holistic concern, COLA is helping them better protect patient safety by embracing lab excellence.

Among private accreditors, COLA prides itself on being the best of the best. One of the ways it achieves that is by advocating on behalf of lab quality standards which go beyond what is required under CLIA or state law.





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TO LEARN MORE ABOUT COLA, VISIT:

www.cola.org
(COLA's corporate website)