

## Legislative oversight of waived testing is imminent.

- The Department of Health and Human Services (HHS) and The Centers for Medicare and Medicaid Services (CMS) have identified vulnerabilities and quality problems with waived laboratories.
- CMS has initiated a Certificate of Waiver Laboratory Project that includes on-site visits to a limited number of waived labs in all 50 states.
- A Centers for Disease Control (CDC) expert group recently recommended a change to the Clinical Laboratory Improvement Amendments (CLIA) statute that currently exempts waived labs from quality control programs, proficiency testing and inspections.

## The facts speak for themselves:

- More than 30% of labs do not routinely check the product insert or instructions for changes to the information
- More than 30% do not perform Quality Control testing as specified by manufacturers' instructions
- Nearly 50% do not document the name, lot number for tests performed

## About COLA

COLA is the premier independent laboratory accrediting organization, dedicated to promoting excellence in laboratory medicine and patient care through a program of voluntary education, consultation and accreditation. COLA offers a wide range of services designed to enable clinical laboratories and staff to meet U.S., CLIA and other regulatory requirements, act in accordance with quality systems and provide the best possible patient care.



Accreditation Education Innovation



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COLA is ISO 9001:2008 certified

The government is performing inspections & putting waived labs under a microscope.

ARE YOU PREPARED?



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Waived testing in point-of-care (POC) settings is an integral part of the everyday care for millions of patients. Once minimally regulated, it is clear that the Federal Government is establishing a new level of oversight in the practice of waived testing. You have to be ready.

We know you want to run a quality lab, but:

- How can you be sure your staff is following manufacturer's instructions for waived testing?
- How do you maintain quality in the face of high staff turnover?
- How do you safeguard patients from an incorrectly administered Rapid HIV test, an uncontrolled Prothrombin Time test or a recalled test kit?

## COLA's Waived/POC Testing Compliance Program:

### *The way to better patient care*

COLA, the nation's largest physician-directed, not-for-profit laboratory accrediting organization, provides a private-sector solution to the problems plaguing the everyday use of waived tests. COLA has the knowledge, experience and expertise to educate and help Certificate of Waiver site personnel improve compliance and quality.

COLA's online portal, COLAcentral, helps you better manage your laboratory and remain in compliance 365 days a year, giving your lab the tools and the education to prevent repeat citations, keep staff CLIA/COLA compliant and dramatically improve practice management.



### *A user-friendly roadmap to compliance and quality*

COLA's program blends education and practice management tools with recognition and achievement.

**Extensive e-learning library** with 60 online courses that allow laboratories to improve testing processes and performance — and new course content is added frequently to keep personnel up to date.

**Exclusive management service** ensures that key activities in the lab are continually monitored. The program includes logs, tools and notifications to assure that the right activity occurs at the right time. Online competency assessments and digital document storage support compliance.

**Ease of use and affordability** make COLA's program an easy decision. The online system is easily accessible from anywhere. It is easy to navigate and becomes part of your everyday work flow. And the system costs only about a dollar a day—a small price to pay for peace of mind.

### **Get professional oversight, not government oversight.**

Be proactive in the face of emerging regulatory reforms by using COLA's program, specifically designed for waived laboratories. It may turn out to be the most important decision you will ever make. Call COLA at 800-981-9883 or visit [www.cola.org](http://www.cola.org)