



A COLA White Paper:

FEDERAL GOVERNMENT QUESTIONS QUALITY IN WAIVED TESTING.



EXECUTIVE SUMMARY

Laboratory testing plays a critical role in the healthcare system, impacting about 70 percent of all diagnostic decisions.¹ Based on 2007 data from the Centers for Medicare and Medicaid (CMS) Online Survey, Certification, and Reporting (OSCAR) database, CDC estimates that approximately 6.8 billion laboratory tests are performed annually in the U.S.²

The number of “waived tests” - simple to perform tests exempt from federal and state laboratory quality requirements - has steadily increased during the past two decades. Often performed in physician-operated laboratories, retail clinics, and other close to patient settings, the number of waived tests has grown from just 9 tests in 1993 to more than 5,400 test systems and 119 analytes.³ From diabetes management and monitoring anti-coagulant therapies, to screening for infectious disease, waived tests are now an integral part of patient care in the United States. Laboratory professional groups have long recognized the need for increased oversight of these “waived” tests, and unfortunately, evidence is mounting that significant quality problems exist in the largely unregulated labs relying on these.

According to a report from the Centers for Disease Control and Prevention, for example, 31% to 43% of waived labs do not follow manufacturer’s instructions.⁴ Some other examples of notable problems among the more than 150,000 waived testing sites⁵ in the U.S. include:

- **More than 20% do not** routinely check the product insert or instructions for changes to the information; (consider the implications of an ignored new sampling technique for a Rapid HIV test)
- **More than 20% do not** perform Quality Control testing as specified by manufacturer’s instructions (consider the implications of an uncontrolled Prothrombin Time test)
- **Nearly half do not** document the name, lot number, and expiration dates for tests performed (consider the implications of a massive recall of problematic test kits)⁶

Evidence is growing that educational interventions and practical tools (e.g. logs for recording key data) have a significant impact on improving compliance with these important activities.

COLA, the nation’s largest physician-directed not-for-profit laboratory accrediting organization provides a private sector solution to the problems encountered by labs relying primarily on waived tests. This program blends education and key practice



management tools, with recognition of achievement. Program participants and Federal Oversight agencies can be confident that these tests are being performed and managed properly. And health practitioners utilizing the results of these tests can be confident in the results.

COLA is leading the charge in ensuring that the voice of the primary care physician is represented to the oversight agencies considering increased regulatory oversight of waived testing, and in the design of physician-centric alternatives with a focus on quality patient care.

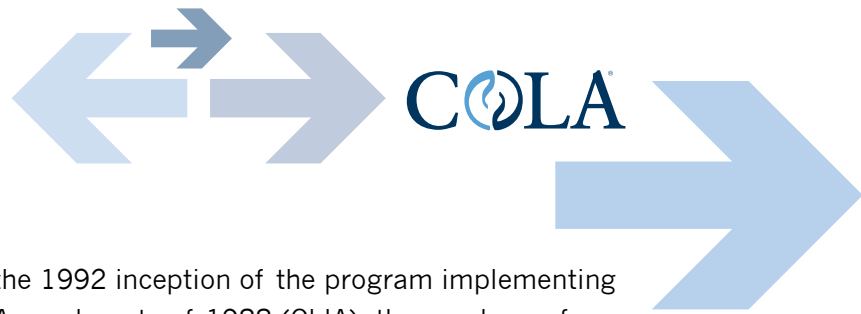
INTRODUCTION

Laboratory testing plays a critical role in health assessment, treatment, monitoring, and ultimately, the public's health. Test results contribute to diagnosis of disease, monitoring of treatment and health status, and population screening for disease. Laboratory testing affects persons in every life stage, and almost everyone will experience having one or more laboratory tests conducted during each year of their life. At least 6.8 billion laboratory tests are performed each year in the United States⁷ and laboratory test results influence approximately 70% of patient management decisions.⁸

Increasingly, these decisions are based on simple tests performed at the point-of-care, using devices that are "waived" from most federal oversight requirements, and are thus designated as *waived tests*. These waivers include no requirements for personnel qualification and training, quality control (QC) (unless specified as required in the test system instructions), proficiency testing (PT), quality assurance, and the need for routine inspection.

THE RISE IN WAIVED TESTING

Advances in technology have made tests simpler and more robust, and this has contributed significantly to utilization of simpler waived methods. In the past, tests such as cholesterol and glucose were performed with instrumentation designed for use by highly trained personnel in traditional clinical laboratory settings. Many tests can now be performed using compact or hand-held devices by personnel with limited experience and training. These advances have enabled more testing to be performed in emergency departments, hospital rooms, and physicians' offices and in non-traditional testing sites such as community counseling centers, pharmacies, nursing homes,



ambulances, and health fairs. Since the 1992 inception of the program implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA), the numbers of waived tests and the sites that perform them have increased dramatically. The list of waived test systems has grown from just 9 tests in 1993 to more than 5,400 test systems and 119 analytes.⁹ This trend is expected to continue as laboratory testing technology continues to evolve.

CLIA REQUIREMENTS FOR WAIVED TESTING

All facilities in the United States that perform laboratory testing on human specimens for health assessment or the diagnosis, prevention, or treatment of disease are regulated under CLIA. The three categories of testing for CLIA purposes are waived, moderate complexity, and high complexity. Waived tests are defined by law as simple laboratory examinations and procedures which:

- Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible;
- Pose no reasonable risk of harm to the patient if the test is performed incorrectly.

Facilities performing only waived tests are only required to obtain a Certificate of Waiver (CW), pay biennial certificate fees, and follow manufacturers' test instructions. However, they must agree to allow inspections. Also, while CLIA's technical requirements for personnel are less stringent for laboratories that perform waived testing than for those that perform moderately complex testing, some states set standards for both types of laboratories that are higher than the minimums required by CLIA.

SCOPE OF WAIVED TESTING

Since 1992, the number of CLIA-waived tests has increased from eight to over 100 tests, representing some 1,600 test systems.¹⁰ During this same period, the number of laboratories issued a Certificate of Waiver has grown exponentially from 20% to 60% of¹¹ the nearly 230,000 laboratory testing sites in the United States.¹² These sites include pediatric, urology, family physician and internal medicine practices as well as urgent care clinics, nursing homes and other primary care sites.



PATIENT SAFETY CONCERNS RELATED TO WAIVED TESTING

While the law and the FDA assert that risk of harm to the patient is insignificant (from incorrect performance of test), these tests are not completely error-proof and are not always performed in settings that use a systems approach to quality and patient safety. Errors can occur anywhere in the testing process, particularly when the manufacturer's instructions are not followed and when testing personnel are not familiar with all aspects of the test system and how testing is integrated into the facility's workflow.

Indeed, some waived tests have potential for serious health impacts if performed incorrectly. For example, results from waived tests are used to adjust medication dosages, such as prothrombin time testing in patients undergoing anticoagulant therapy, and glucose monitoring in diabetics. In addition, erroneous results from diagnostic tests, such as those for the human immunodeficiency virus (HIV) antibody, can have innumerable unintended consequences.

The lack of oversight and requirements for personnel qualifications and training for an increasingly large number of Certificate of Waiver sites is also a concern, and could contribute to errors and patient harm. Often, the personnel performing these tests do not understand the potential negative impacts of improper sampling and testing technique and its relation to accurate results.

BACKGROUND

In 2001, the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) published a report that identified vulnerabilities in the program enrollment and certification process of the CLIA program, including oversight of Waived and Provider-Performed Microscopy Procedures (PPMP) labs, particularly due to the lack of routine inspection visits. It recommended several steps to improve testing at waived laboratories, including increased educational outreach, periodic self-assessment, and random surveys of some waived laboratories each year.

CMS, which had conducted its own on-site surveys of a representative sample of Certificate of Waiver sites in 10 states during 1999-2001 to assess the quality of testing in these sites, concurred with the OIG's findings. In the case of 100 Certificate of Waiver and PPMP laboratories visited in 1999, for example, CMS had found that 50% had quality problems. During a 2000-2001 CMS Expanded Pilot Study, 32% of the 436 labs surveyed were determined to have quality problems.¹³



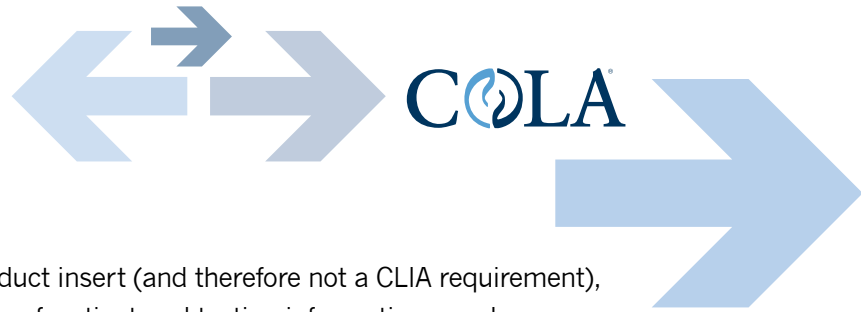
As a result, during 2002-2004, CMS conducted nationwide on-site random surveys of Certificate of Waiver facilities to collect additional data and simultaneously encourage improvement through educational outreach, promote good laboratory practices, and make recommendations on the basis of cumulative survey findings. The data collected from these surveys, along with data on waived testing practices gathered through CDC-funded studies conducted during 1999-2003 by several state health departments (collectively referred to as the Laboratory Medicine Sentinel Monitoring Network or LMSMN), support the initial CMS findings of gaps in good laboratory practices in these sites.

CMS AND CDC FINDINGS

The findings from the CMS 2002-2004 surveys and CDC-funded studies indicate that most laboratory directors and testing personnel at waived sites did not have formal laboratory training or testing experience,” and there was high turnover of personnel.¹⁴ Also, in some instances, Certificate of Waiver sites were determined to be performing testing that was a potential imminent and serious threat to the public’s health because they were performing non-waived testing in the absence of CLIA-required quality measures. The CMS surveys indicated that 5% of Certificate of Waiver sites were conducting tests that were not actually “waived,”¹⁵ and were therefore outside the scope of the laboratory.

Additionally, of the Certificate of Waiver facilities CMS surveyed:

- 12% did not have the most recent instructions for the waived test systems they were using
- 21% reported they did not routinely check the product insert or instructions for changes to the information
- 21% did not perform Quality Control testing as specified by manufacturers’ instructions
- 18% did not use correct terminology or units of measure when reporting results
- 6% failed to adhere to proper expiration dates for the test system, reagents, or control materials
- 3% failed to adhere to the storage conditions as described in the product insert
- 6% did not perform follow-up confirmatory tests as specified in the instructions
- 5% did not perform function checks or calibration checks to ensure the test system was operating correctly¹⁶



Although not usually specified in the product insert (and therefore not a CLIA requirement), proper documentation and recordkeeping of patient and testing information are also important elements of good laboratory practices. CMS surveys of the Certificate of Waiver sites indicated that:

- 45% did not document the name, lot number, and expiration dates for tests performed;
- 35% did not maintain logs with records of their Quality Control testing
- 31% did not maintain a log or record of tests performed
- 9% did not require a requisition or test orders be documented in a patient chart before performing a test.¹⁷

The CDC-funded study also reported strikingly similar findings in its 2004 report. Among the waived laboratories surveyed, the study found:

- High staff turnover
- Lack of formal laboratory education
- Limited training in test performance & QA
- Lack of awareness concerning “good laboratory practice”
- Partial compliance with manufacturers’ Quality Control instructions (approx. 55% - 60%)¹⁸

STUDY CONCLUSIONS AND MARKETPLACE RESPONSES

CMS studies have demonstrated that a persistent percentage of Certificate of Waiver sites do not meet minimal requirements, and are not aware of recommended practices to help ensure quality testing. The studies indicate a need for educational efforts to Certificate of Waiver site directors and testing personnel about the importance of following manufacturer’s instructions, adhering to expiration dates, performing Quality Control testing, and proper documentation and recordkeeping.

The study findings have resulted in several industry responses to date. CMS continues to randomly survey 2% of all Certificate of Waiver sites as part of its ongoing nationwide study of waived testing facilities. Statistics suggest that this ongoing surveillance, combined with educational outreach is having an impact. For example, in fiscal year 2006, CMS data shows that nearly 85% of labs inspected and provided educational guidance showed at least temporary improvement upon revisit.¹⁹

Nevertheless, industry experts argue, even these lowered rates are not low enough. According to CMS, in 2012 there were 229,815 laboratories in the U.S., of which 150,256 were Certificate of Waiver sites.²⁰ Stated another way, this means that **some**



65% of laboratories in the U.S. do not have any routine oversight. While CMS noted some improvement in overall laboratory performance in leading deficiency areas, laboratory quality consulting firm Westgard QC points out that even if only 5-6% of waived labs aren't performing, for example, Analytic Systems QA properly, that can still translate into thousands of labs operating without proper quality control in place.

GOOD LABORATORY PRACTICES RECOMMENDATIONS

In response to the CMS and CDC survey findings, the Clinical Laboratory Improvement Advisory Committee (CLIAAC) recommended and the CDC published a series of guidelines for good laboratory practices in 2005. These recommendations are intended to promote the use of good laboratory practices by physicians, nurses, and other providers of waived testing in a variety of Certificate of Waiver sites. They address decisions that need to be made and steps to be taken as a facility begins offering waived testing or adds a new waived test, develops procedures and trains personnel. They also describe recommended practices for each phase of the total testing process, including the important steps or activities before, during, and after testing, which are critical to providing quality testing. By implementing these recommendations, Certificate of Waiver sites can improve quality, reduce testing errors, and enhance patient safety.

More recently, the Centers for Disease Control and Prevention (CDC) have joined forces with CMS to educate waived laboratory personnel on Good Laboratory Practices for Waived Testing (GLP). With input from CMS, the CDC created an educational waived testing program, titled "Ready? Set? Test!" that consists of a poster that can be displayed in waived laboratories, an educational booklet, and an online course. The program booklet provides tips for waived testing personnel to follow throughout the testing process. It also includes several examples of charts, logs, and other job aids that can be personalized for use in their laboratory. Even though many of these tips are well known to personnel with a strong laboratory medicine background, the program is a valuable resource for its targeted audience: personnel performing waived testing who have little or no background in laboratory medicine.

A related educational booklet, "To Test or Not to Test," describes considerations and preparations needed prior to performing waived testing and may assist those who want to implement and oversee waived testing or offer a new test under a CLIA Certificate of Waiver. The booklet contains tips, reminders, and resources along with forms and examples for use in waived testing sites.



While stating that “education is effective” in improving Certificate of Waiver laboratories’ performance, CMS’s resources in this area are “lacking,” according to the agency. And meanwhile, the problem of unregulated waived testing is growing, as the number of both Certificate of Waiver labs and new waived test methods continue to increase exponentially.

GOVERNMENT OVERSIGHT IMMINENT

It is clear, many industry experts agree, that government oversight will be required to fully address the problems caused by largely unregulated waived testing. Even a CDC expert group seems to acknowledge this in a recent report on proficiency testing, where it made the following recommendation: “Develop a process to assure that all clinical laboratories, including those that perform waived tests, participate in PT.” This recommendation requires a change in the CLIA statute (law) (Public Health Service Act: Section 353 [263a][d][2][C]) that specifically exempts waived laboratories from standards (i.e. Quality Control programs, PT, and inspections).” ²¹

Additionally, COLA staff has communicated with a cross-section of individuals directly involved with the laboratory industry, including laboratorians, manufacturers, and regulators. There is a consensus that a new testing tool for CBC’s could meet the criteria for waiver, affecting the status of a huge number of labs presently regulated under CLIA. Such a change could effectively restore the scope of federal regulation of labs to what it was in 1967, when the original CLIA law was enacted and have a significant clinical impact on patient care.

COLA also learned that, in 2011, the Obama Administration initiated a process through which proposed legislation addressing the regulation of waived tests was developed. While such legislation has yet to be introduced in Congress, many in the regulated community believe that the regulation of waived testing is necessary to ensure high quality patient care.

THE CHANGING POLITICAL LANDSCAPE

This drive towards increased regulation of waived laboratories is also being fueled by the philosophical shift related to the current political administration, which has ushered in a period of fundamental change in the U.S. health care system through enactment of the Affordable Care Act. While waived testing is not at the top of the health care reform list, it is inevitable that an issue with such patient care quality implications will be addressed by the Obama Administration -- sooner rather than later.



A SOLUTION IS ALREADY AT HAND

If legislative oversight of waived testing is imminent -- and governmental resources to help labs prepare are, by CMS's admission, lacking -- what, then, can the industry do to prepare for this new environment?

In fact, a solution already exists in the form of COLA, a leading laboratory accreditation organization which is dedicated to "promoting excellence in laboratory medicine and patient care through a program of voluntary education, consultation, and accreditation." Based on its belief that education is the way to achieve excellence in healthcare, COLA has built an extensive library of tools that allow practices to improve their testing processes.

BACKED BY EXPERIENCED STAFF AND MANAGEMENT EXPERTISE

COLA's legacy was built by working with labs that were previously unregulated by providing an educational, user friendly, simple roadmap to compliance and lab quality. With an accreditation program that has helped over 35,000 laboratories maintain compliance with CLIA since 1993, COLA also has the knowledge, experience, and expertise to educate and provide assistance to Certificate of Waiver site personnel.

COLA's solutions provide accreditation, competency assessment and maintenance tools, and management services that support the physician's role in quality management of waived testing. These solutions include a variety of online educational materials and courses about waived testing and the importance of performing it correctly for accurate results. COLA also offers waived labs access to its new laboratory recognition program called Patient Centered Laboratory Excellence (PCLE), which emphasizes continuous good laboratory practices above and beyond current regulatory requirements for moderate and high complexity labs. COLA is currently offering the program through a partnership with the American College of Physicians (ACP) to ACP members. The joint initiative is designed to assist Patient Centered Medical Home practices in delivering quality and value-driven laboratory medicine to their patients.



CONCLUSION

The findings of multiple surveys of sites performing waived testing throughout the United States lead to similar and alarming conclusions about lapses in quality in Certificate of Waiver sites. The studies highlight the need for additional education and training related to waived testing for Certificate of Waiver site directors and testing personnel.

While CMS provides some educational resources, the agency characterizes its resources in this area as “lacking.” In the meantime, the problem of unregulated waived testing continues to grow, with the number of both Certificate of Waiver labs and new waived test methods increasing dramatically. Many industry experts believe that government oversight of the waived testing sector is inevitable, especially as the new political administration seeks to make sweeping changes to the U.S. health care system.

COLA offers extensive tools that provide the laboratory industry a ready-made answer to the growing problem of how to provide oversight of waived testing. By encouraging the widespread use of these COLA tools by waived laboratories everywhere in the U.S., laboratory and medical industry leaders, manufacturers, states, the CDC, CMS and other stakeholders will be able to proactively manage this important health care issue.

Our objectives are threefold: To ensure better patient outcomes by ensuring a culture of quality in the performance of waived tests; to help laboratories prepare for the day in which federal regulation does come, and to establish a model which Congress and regulators may look to when crafting a regulatory system for waived tests.

For additional information or to comment on this report, please contact Doug Beigel, CEO of COLA, at 410-381-8794 or dbeigel@cola.org



CITATIONS

- (1) The American Clinical Laboratory Association.
- (2) "Laboratory Medicine: A National Status Report," The Lewin Group, 2007
- (3) <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfclia/analyteswaived.cfm>
- (4) "COLA Patient Centered Laboratory Excellence Program", 8/12
- (5) "COLA Patient Centered Laboratory Excellence Program," 8/12
- (6) CDC's "Good Laboratory Practices for Waived Testing Sites," Page 5, 11/05
- (7) Laboratory Medicine: A National Status Report," The Lewin Group, 2007
- (8) American Clinical Laboratory Association.
- (9) <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfclia/analyteswaived.cfm>
- (10) Washington G-2 Reports: CLIA Compliance & Proficiency Testing: What's New at CMS & FDA for 2009?" 2/09
- (11) Washington G-2 Reports: CLIA Compliance & Proficiency Testing: What's New at CMS & FDA for 2009?" 2/09
- (12) COLA Patient Centered Laboratory Excellence Program," 8/12; Note: G-2 presentation used the figure >209,000; M. Nichols updated this to reflect statistic in COLA presentation
- (13) Washington G-2 Reports: CLIA Compliance & Proficiency Testing: What's New at CMS & FDA for 2009?" 2/09
- (14) CDC's "Good Laboratory Practices for Waived Testing Sites," Page 6, 11/05
- (15) CDC's "Good Laboratory Practices for Waived Testing Sites," Page 6, 11/05
- (16) CDC's "Good Laboratory Practices for Waived Testing Sites," Pages 5- 6, 11/05
- (17) CDC's "Good Laboratory Practices for Waived Testing Sites," Page 5, 11/05
- (18) "CDC Update: Waived Testing," CLIAC Meeting, 9/04, Devery Howerton, Ph.D., Chief, Laboratory Practice Evaluation and Genomics Branch, DLS
- (19) Washington G-2 Reports: CLIA Compliance & Proficiency Testing: What's New at CMS & FDA for 2009?" 2/09
- (20) COLA Patient Centered Laboratory Excellence Program," 8/12
- (21) "Review of Proficiency Testing Services for Clinical Laboratories in the United States," April, 2008, Prepared for the Division of Laboratory Systems, Centers for Disease Control and Prevention

Some of the information in this report was gleaned from "Good Laboratory Practices for Waived Testing Sites: Survey Findings from Testing Sites Holding a Certificate of Waiver Under the Clinical Laboratory Improvement Amendments of 1988 and Recommendations for Promoting Quality Testing," which appeared in the CDC's MMWR, Reports and Recommendations, November 11, 2005. The material in the MMWR report originated in the Coordinating Center for Health Information and Service, Steven L. Solomon, MD, Director; National Center for Health Marketing, Jay M. Bernhardt, PhD, Director; and the Division of Public Health Partnerships, Robert Martin, DrPH, Director.



ABOUT COLA

In 1988, a group of physicians founded COLA as a private alternative to help Physician Office Laboratories (POLs) stay in compliance with newly enacted Clinical Laboratory Improvement Amendments (CLIA). In 1993, the Health Care Financing Administration (now CMS) granted COLA deeming authority in all 50 states under CLIA, and in 1997 the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) also recognized COLA's laboratory accreditation program.

After 35,000 surveys in which COLA's practical, educational accreditation methods helped physician office laboratories stay in compliance with CLIA, COLA expanded its program offerings to include hospital and independent laboratories.

Today, COLA accredits almost 8,000 medical laboratories and provides the clinical laboratory with a program of education, consultation, and accreditation to meet U.S. CLIA and other regulatory requirements, act in accordance with quality systems, and provide the best possible patient care. COLA's Board of Directors includes representatives of such leading health care organizations as the American College of Physicians, the American Academy of Family Physicians, and the American Medical Association. For more information about COLA accreditation services and educational products, and online educational opportunities, please call 800-981-9883 or visit COLA's web site at www.cola.org or www.colainsider.org.

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