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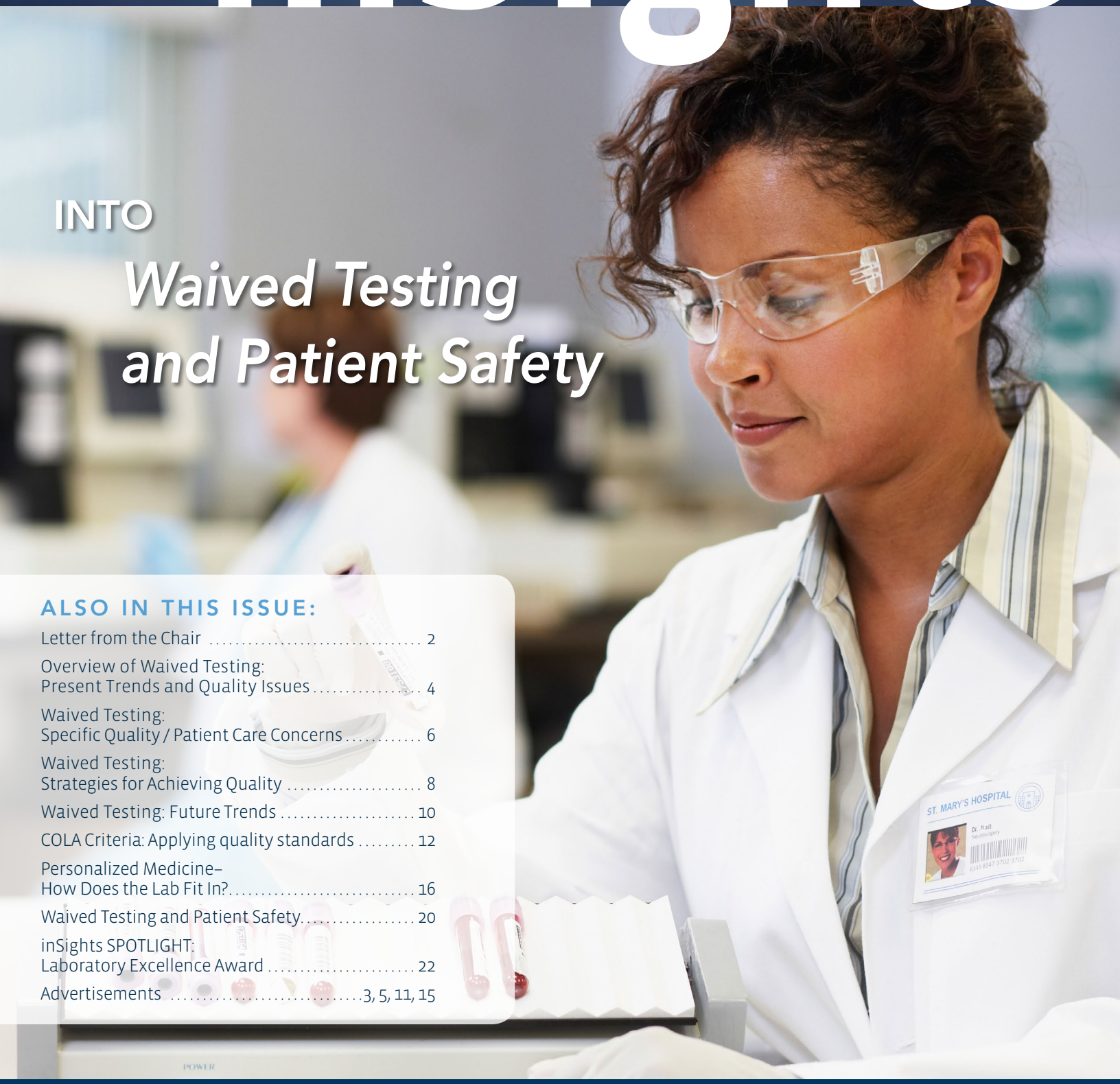

INTO

Waived Testing and Patient Safety

ALSO IN THIS ISSUE:

FROM THE CHAIR

Richard A. Wherry, M.D.
Chair, COLA Board of Director

In this issue of Insights we explore the impact of waived testing on patient care. Technological advances are resulting in continued growth in the variety and scope of waived testing, but concerns over quality issues have cast a shadow over this progress. This issue explores all aspects of this high-growth, high-impact area of laboratory medicine.

Waived Testing Overview provides an overview of the growth and popularity of waived testing. Discussion includes how new technology in waived testing reflects changes in how medical care is delivered, the evolving role of the laboratory, and how this testing is an important driver for the globalization of laboratory testing. However, all is not rosy as concerns over the quality of testing are growing with the prospect of increased oversight and regulation. How will this affect the future of waived testing?

Present Trends and Quality Issues With over 60% of all CLIA certified laboratories possessing a Certificate of Waiver, we can no longer just focus on laboratories performing non-waived testing. Since the concept of waived testing was created almost 25 years ago, the number of waived certified tests has grown from 9 to almost 119; and test systems for this category of testing are approaching 2,000. Studies by the CMS and the CDC have confirmed a significantly higher level of quality issues in waived-only laboratories, prompting calls for added oversight and regulation.

Specific Quality and Patient Care Concerns are discussed in detail, from the lack of laboratory director qualifications to provide proper oversight, to the types and extent of quality lapses found in waived laboratories. These figures are derived from random surveys conducted by both CMS and in-state health department surveyors. From these figures, we come to certain conclusion about what corrective actions are needed.

Strategies for Achieving Quality delineates the ways that progress toward improving quality testing and patient safety can be achieved. These include discussions of management responsibility; the testing environment; personnel issues and cost considerations. Personnel issues include proper training and competency assessments, staffing levels, and communication channels.

Future Trends discussed the key role of waived testing in Point of Care Testing (POCT), and how POCT is revolutionizing how health care is delivered, not only domestically, but internationally. We also discuss how important POCT is for providing medical care at the sites of disasters, epidemics and conflict.

COLA Criteria for Waived Testing reflect COLA's efforts to bring quality standards to our Accreditation program for the waived testing performed in our laboratories. These ten criteria specifically address issues of personnel training and competency, documentation, test management, proficiency testing, results reporting. All phases of testing are addressed to assist our laboratories to provide the highest quality possible for the waived testing performed.

Our Feature Article, *Personalized Medicine and the Role of the Laboratory* provides an in depth discussion of the concept of personalized medicine. Personalized medicine is an evolving field of medicine defined as the tailoring of medical treatment to the individual characteristics, needs and preferences of each patient during all stages of care, including prevention, diagnosis, treatment, and follow up. This approach relies on understanding how a person's unique molecular and genetic profile makes them susceptible to certain diseases. The evolving landscape of what this means, and the role of the laboratory is discussed. Personalized medicine means big changes for how clinical laboratories operate.

Thus, this issue of Insights is devoted to examinations of two of the major forces impacting laboratory medicine: the growth of Waived testing, and the development of Personalized Medicine. Both will continue to require continued revisiting of how we run our laboratories, how we regulate them, and how we can accommodate all the changes ahead.

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Overview of Waived Testing: Present Trends and Quality Issues[1]

The Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) created the concept of "waived tests" which are defined as tests that are so simple to perform, and produce accurate results so reliably as to render the likelihood of erroneous results negligible; and which also pose no reasonable risk of harm to the patient if the test is performed incorrectly. As a result, these tests are exempt ("waived") from federal requirements for personnel qualification and training, quality control (except as specified by the manufacturer), proficiency testing, quality assurance, and the need for routine inspection. This category also includes tests which have been cleared by the FDA for home use.

All facilities that perform testing on human specimens for health assessment, diagnosis, prevention, or the treatment of disease are regulated under CLIA. This includes laboratories performing only waived testing, which operate under a Certificate of Waiver. There are just four CLIA requirements for these labs:

- Renew their Certificate of Waiver every two years
- Perform only waived testing
- Follow instructions in the most current manufacturer's product insert without modification, when performing the test
- Permit announced or unannounced inspection by CMS representatives.

Since the inception of CLIA 88 and the concept of waived testing, technological advances that simplified test processes and increased reliability of test results, have led to a dramatic increase in the number of approved waived tests from 9 to 119; and the number of test systems to over 1600. This in turn, has resulted in an equally dramatic increase in the number and proportion of all clinical laboratories and facilities conducting waived testing to over 60% of the nearly 230,000 CLIA certified facilities.

As the number of approved analytes for waived testing has increased, the potential for serious impact on healthcare has also increased. Think of the consequences of incorrect Prothrombin times, Glucose values, Electrolytes, and HIV screens for patient care.

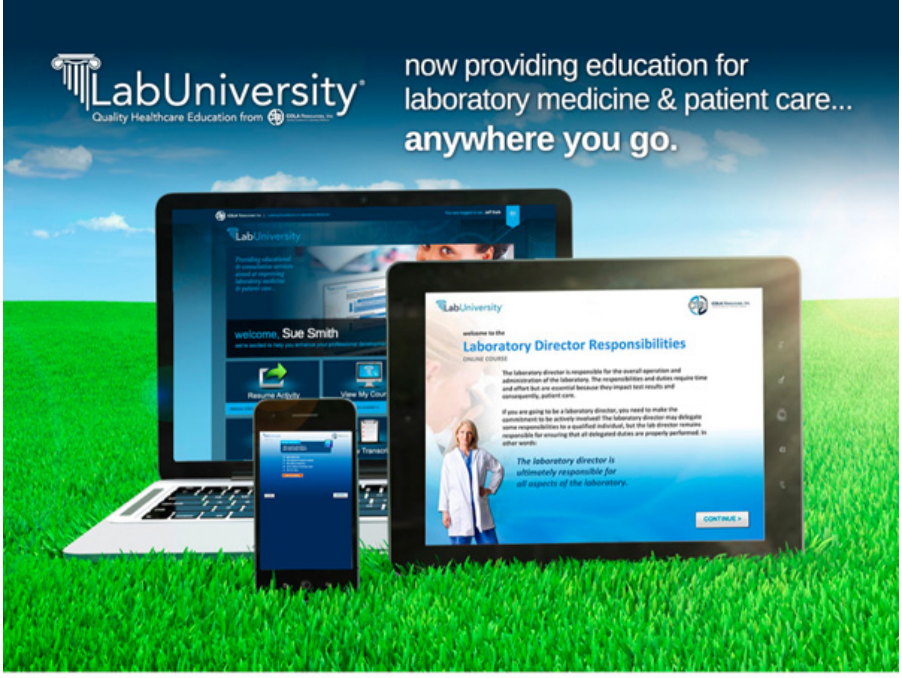
As efforts intensify to reduce medical errors, improve health-care quality, and increase patient safety, there is a renewed focus on how to better monitor waived testing.

Studies conducted by both CMS and the CDC between 2001 and 2004 have shown a higher level of quality issues in waived only laboratories that were randomly surveyed. These included lack of available written procedures, personnel training, competency assessments, performance of required quality control, proper regard for reagent expiration dates and storage requirements; and failure to enter results of tests performed into electronic medical records. Errors can occur in any phase of the testing process, and have serious consequences for patient care.

It has become increasingly clear that additional CMS oversight is required to address these quality issues that persist in significant numbers of waived laboratories.

RESOURCES:

1. CDC MMWR November 11, 2005 /54(RR13): "Good Laboratory Practices For Waived Test Systems"; 1-25. http://cdc.gov/mmwr/preview/mmwrhtml/rr5413a l.htm.
2. COLA White Paper: "Federal Government Questions Quality In Waived Testing. The Hard Facts and What Can Laboratories Do Now?" 2013



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Waived Testing: Specific Quality / Patient Care Concerns[1]

Laboratory professionals have long expressed concern about the quality of testing performed in waived laboratories since waived testing is exempt from federal requirements for personnel qualification and training, quality control (except as specified by the manufacturer), proficiency testing, quality assurance, and the need for routine inspection. The lack of personnel qualification, training and competency standards is the progenitor of many of these concerns.

As the number of waived testing sites increased dramatically, these concerns led CMS to conduct on-site surveys of a representative sample of these sites in ten states from 1999-2001. These pilot surveys identified quality issues that could result in medical errors. Contributing factors included inadequate training in good laboratory practices, and high turnover rates of testing personnel. As a result from 2002-2004, CMS conducted nationwide on-site surveys of Certificate of Waiver facilities to collect additional data that would provide an assessment of testing, promote good laboratory practices, encourage educational outreach, and make recommendations. The data collected supported the initial findings of gaps in good laboratory practices at these sites. In addition, a 2001 report issued by the HHS office of the Inspector General identified the lack of routine on site visits to Certificate of Waiver sites by surveyors from state agencies or private accreditation organizations as representing vulnerabilities in these sites.

Since CMS has no education or training requirements for either the director or testing personnel of Certificate of Waiver laboratories, the data collected showed sharp divergences from CLIA regulated non-waived laboratories: CMS surveys of Certificate of Waiver laboratories showed 69% of laboratory directors were physicians; followed by nurses at 17%.

Subsequent on-site surveys of waived laboratories by state health agencies showed that 59% of laboratory directors were physicians; and 41% had other backgrounds or degrees.

The top categories of Certificate of Waiver laboratory testing personnel, according to CMS data, were nurses (46%), medical assistants (25%), physicians (9%), and (non-specific) high schools graduates (7%). Only 2% of the laboratory directors and testing personnel were trained laboratory personnel (Medical Technologists/CLS, and Medical Laboratory Technicians/CLT).

An interesting finding is that the largest percentage of personnel training in waived labs was conducted by nurses, followed by manufacturer's representatives. A significant number of testing staff were self-trained. The majority of training took place in a day or less.

While the majority of Certificate of Waiver laboratories were aware of and followed some practices to ensure the accuracy and reliability of their testing, lapses in quality were identified at certain sites, some of which could result in patient harm. For example, 5% of these laboratories surveyed by CMS were determined to be performing tests that were not actually "waived," and were therefore outside the scope of the laboratory; and thus were performed in the absence of CLIA-required quality measures.

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 manufacturer's 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 correctly

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.

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 manufacturer's Quality Control instructions (approx. 55% - 60%)

As you can see, so many of these issues can be traced back to our starting point: lack of CLIA requirements for personnel qualification, training and competency assessment.

Strategies for addressing these issues must begin with instituting good laboratory practices for hiring qualified personnel, properly training them, and assessing competency.

RESOURCES:

1. CDC MMWR November 11, 2005 /54(RR13): "Good Laboratory Practices For Waived Test Systems"; 1-25. http://cdc.gov/mmwr/preview/mmwrhtml/rr5413a l.htm.
2. COLA White Paper: "Federal Government Questions Quality In Waived Testing. The Hard Facts and What Can Laboratories Do Now?" 2013

Waived Testing: Strategies for Achieving Quality[1]

Because surveying all waived sites is not feasible, the proposed actions to improve and promote quality testing in these sites emphasize the importance of training and competency for site directors and testing personnel. To provide a guide that can be adapted for use, either in part or as a whole, by persons or facilities considering the initiation of waived testing and personnel performing waived testing, CLIAC provided recommendations for good laboratory practices. By implementing these recommendations, Certificate of Waiver sites could improve quality, reduce testing errors, and enhance patient safety.

Considerations Before Introducing Waived Testing, Offering a New Waived Test, or Improving Your Present Operation:

Forethought, planning, and preparation are critical for achieving high-quality waived testing in any type of setting. Questions to address include the following:

- Management responsibility for testing. Who will be responsible and accountable for testing oversight at this waived site, and does this person have the appropriate training for making decisions on testing?
- Safety. What are the safety considerations for persons conducting testing and those being tested?
- Testing space and facilities. What are the physical and environmental requirements for testing?
- Staffing. Are there sufficient personnel to conduct testing, and how will they be trained and maintain testing competency?
- Documents and records. What written documentation will be needed, and how will test records be maintained?

Management Responsibility

Each testing site should identify at least one person responsible for testing oversight and decision-making. In POLs, this might be a physician or someone in a senior management position who has the appropriate background and knowledge to make decisions about laboratory testing. The management staff should demonstrate a commitment to the quality of testing service by promoting good laboratory practices.

Testing Environment

Some tests have specific environmental requirements described in the manufacturer's product insert that need to be met to ensure reliable test results. Factors to consider include:

- Humidity – Unusually high, low, or extreme fluctuations in humidity can cause deterioration of reagents and test components, affect the rate of chemical reactions and specimen interaction, or make test endpoints blurred and difficult to read.
- Temperature – Temperature ranges for storage of test components and controls and for test performance are defined by the manufacturer to maintain test integrity. Extreme temperatures can degrade reagents and test components, impact reaction times, cause premature expiration of test kits, and affect the test results.
- Lighting – Inadequate lighting can negatively affect specimen collection, test performance, and interpretation of test results.
- Work space – Work surfaces should be stable and level and be able to be adequately disinfected; work space should be adequate in size for patient confidentiality, ease of specimen collection, test performance, and storage of supplies and records.

Cost Considerations

A fiscal assessment of testing is part of a good management program. Before offering a new test, consider the level of reimbursement and factors that contribute to total test cost. These factors include:

- Test kits or instruments, supplies not provided with the test, control and calibration materials, inventory requirements for anticipated test volume (including seasonal testing), and the shelf life of test components and supplies.
- Equipment maintenance, such as repairs or preventive maintenance contracts.
- Additional safety and biohazard equipment.
- Personnel training, competency assessment, and the potential need for additional personnel.
- Recordkeeping and information systems.

Personnel Considerations

Personnel competency and turnover are important factors affecting the quality and reliability of waived testing results. No CLIA requirements exist for waived testing personnel qualifications; however, applicable state or local personnel

regulations must be met. Personnel issues to consider include:

- Is staffing adequate?
  - Determine whether employees have sufficient time and skills to reliably perform all activities needed for testing in addition to their other duties.
  - Be aware that temporary or part time personnel might be less proficient in performing testing.
  - Evaluate staff for color-blindness because this can limit their ability to interpret test results based on color endpoints.
- How much training will be needed?
  - Take into account the staff turnover rate and the ongoing need to provide training for new personnel.
  - Factor in the time and resources for adequate training and competency evaluation of staff before they perform testing.
  - Consider how testing personnel will maintain competency, especially when testing volume is low.

Developing Procedures and Training Personnel

It is good laboratory practice to develop written policies and procedures so that responsibilities and testing instructions are clearly described for the testing personnel and facility director. The testing procedures form the basis of training for testing personnel. These procedures should be derived from the manufacturer's instructions and should be in a language understandable to testing personnel.

Personnel Training

Trained and competent testing personnel are essential to good quality testing and patient care. Personnel should be trained and competent in each test they will perform before reporting patient results. In addition, training should include aspects of safety (including Universal Precautions) and QC. The site director or other person responsible for overseeing testing should ensure that testing personnel receive adequate training and are competent to perform the procedures for which they are responsible. Training checklists are helpful to ensure the training process is comprehensive and documented.

The Training Process

Training should be provided by a qualified person (e.g., experienced co-worker, facility expert, or outside consultant) with knowledge of the test performance, good laboratory practices, and the ability to evaluate the efficacy of the training.

Competency Assessment

To ensure testing procedures are performed consistently and accurately, periodic evaluation of competency is recommended, with retraining, as needed, on the basis of results of the competency assessment. Assessment activities should be conducted in a positive manner with an emphasis on education and promoting good testing practices. Competency can be evaluated by methods such as observation, evaluating adequacy of documentation, or the introduction of mock specimens by testing control materials or previously tested patient specimens. External quality assessment or evaluation programs, such as voluntary PT programs, are another resource for assessment.

Additional Measures to Help Testing Staff Ensure Reliable Results

The site director or person overseeing testing should promote quality testing and encourage staff to ask questions and seek help when they have concerns. Recommendations include:

- Identifying a resource person or expert (e.g., a consultant or manufacturer's technical representative), available either off-site or on-site, to answer questions and be of assistance.
- Posting telephone numbers for manufacturers' technical assistance representatives.
- Designating an appropriately trained person, who understands the responsibilities and impact of changing from one test system to another, to discuss new products with sales representatives.

This is a fairly extensive list of actions that a Certificate of Waiver facility can take. It is very comprehensive, indicating the systemic nature of any laboratory operation. Quality failures often are not due to just a single factor, but to a multiplicity of factors that need to be addressed, for a successful outcome.

RESOURCES:

1. CDC MMWR November 11, 2005 /54(RR13): "Good Laboratory Practices For Waived Test Systems"; 1-25. http://cdc.gov/mmwr/preview/mmwrhtml/rr5413a l.htm.
2. COLA White Paper: "Federal Government Questions Quality In Waived Testing. The Hard Facts and What Can Laboratories Do Now?" 2013

Waived Testing: Future Trends[1]

There has been rapid innovation both in the range and complexity of diagnostic tests, and in laboratory test methods and techniques. Advances in diagnostic products make it possible to detect diseases early, when they often can be best treated. Advances in laboratory medicine have also made lab tests easier to use and less subject to user error, they have led to more precise and timelier results, and they have helped transform medical practice. Key trends in diagnostic test innovation include: detecting disease before symptoms appear; predicting beneficial and adverse treatment effects; enabling personalized treatment regimens; facilitating point-of-care testing; and enabling home testing.

Technological advances are changing not only the way diagnostic tests are performed, but also the practice of medicine itself. Improvements in diagnostic tests and the methods to perform them provide increasingly more precise and timely information to assist medical caregivers to prevent and diagnose disease, monitor its progression, and guide therapeutic options. Laboratory innovations have resulted in many new tests that are more efficient and automated, and less subject to user error. In addition, many tests have become less invasive or easier to administer, causing less discomfort to patients.

A major driver for the growth and expansion of waived testing is the growth of Point-of-care testing.

Tests are no longer confined to the laboratory. Point-of-care tests can now provide needed information close to where health care is delivered, facilitating more rapid diagnoses and treatment decisions and improved patient compliance with physicians' recommendations.

Technological innovations have led to point-of-care tests that are available for use close to where diagnostic and treatment decisions are made—at the patient's bedside, in the emergency room or clinic, at the workplace, in an exam room of a physician's office, and even at home. Point-of-care tests eliminate the need for trips to and from the central laboratory (and specimen collection sites that are run by laboratories). These tests enable physicians to make more rapid diagnoses and treatment decisions, and they improve patient compliance with physicians' recommendations. The demand for point-of-care tests has spurred the development of smaller, faster, and easier to use tests that are more sophisticated in design than tests traditionally found in laboratories. Having this information available near the patient permits the physician to begin necessary treatment more quickly.

While less than 10 percent of lab tests are performed in a physician office lab, these tests can provide immediate feedback to the clinician, offering the opportunity to address health care problems while the patient is still in the office. Some of the tests performed in the office include streptococcus testing, HIV (AIDS) testing, INR (coagulation) testing for coumadin and pregnancy testing. There are waived test methodologies for all of these. The ability to immediately treat the patient, without having to send a sample to a central hospital laboratory, can be critical to the patient's well-being. As an example, a positive test for strep can allow the clinician to immediately prescribe antibiotics, catching an infection before it becomes severe, with potential health consequences (or ruling out strep and avoiding unnecessary use of antibiotics).

Garnering information with a point-of-care test often allows immediate treatment, which avoids requiring the patient to make multiple trips to the physician office and pharmacy, saving time for both the patient and the clinician. Accurate diagnostic information at the point-of-care saves critical medical resources and improves both patient and clinician satisfaction. In light of the role of waived testing in the healthcare delivery system and overall benefits of these technologies, availability of and timely access to these technologies will continue to be important to meet the needs of patients and clinicians for rapid and reliable testing.

International Innovation Impact of Point-of-care testing and Waived Testing Technology

Site Laboratories:

Technology has allowed the development of smaller, limited menu laboratories that can perform diagnostic testing. These smaller site laboratories are key to improving global laboratory capacity, especially in countries with poor transportation infrastructure. These laboratories have the responsibility for sample collection, initial processing if required, and storage and shipment of specimens to larger central or reference laboratories. The quality of the laboratory test result is only as good as the quality of the specimen, and this is controlled by the site lab. In addition, important POC/ waived testing is often performed, such as rapid HIV, pregnancy tests, hemoglobin levels, etc., and it is designed for regions where full laboratory services are not available. In these areas, tracking diseases that can be diagnosed through multiple/alternative test methods are particularly relevant to this approach.

RESOURCES:

1. CDC MMWR November 11, 2005 /54(RR13): "Good Laboratory Practices For Waived Test Systems"; 1-25. http://cdc.gov/mmwr/preview/mmwrhtml/rr5413a l.htm.
2. COLA White Paper: "Federal Government Questions Quality In Waived Testing. The Hard Facts and What Can Laboratories Do Now?" 2013

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COLA Criteria: *Applying quality standards*

Since the inception of waived testing as a category of laboratory analysis that is not subject to CLIA requirements for personnel qualifications, training and competency, proficiency testing, quality control (except for following manufacturer's instructions), and quality assessment, evidence has accumulated indicating serious quality challenges that can significantly impact patient care.

At a Clinical Laboratory Improvement Advisory Committee (CLIAC) meeting in 2013, COLA Board member, Dr. Verlin Janzen outlined these challenges to quality found in waived laboratory sites:

- High staff turnover
- Failure to adequately train personnel and determine if competency is maintained
- Failure to perform/record/respond to Quality Control as specified
- Lack of knowledgeable lab director or involvement
- Failure to document test, lot number or expiration date
- Failure to follow current instrument or kit instructions
- Pre-and post-analytical errors
- Waived sites performing non-waived testing
- Failure to enter results into electronic health records.

As a result of these concerns, COLA has added a new group of criteria (WAV – Waived Testing) to provide additional guidance to laboratories performing waived testing. The good laboratory practices outlined in these new criteria encompass activities and procedures designed with the goal of achieving accurate and reliable test results.

WAV 1
Addresses the requirement to always follow manufacturer's instructions in the performance of the test and storage requirements for kits, reagents and controls.

Are manufacturer's instructions followed in the performance of each waived testing procedure and are all kits, reagents, and controls stored according to manufacturer recommendations?

Staff performing laboratory testing need to follow all procedures and manufacturer recommendations as found in procedure manuals, package inserts, and/or instrument manuals.

Modifications made by the laboratory to the manufacturer's procedure will, by default, change the classification of the laboratory test to high complexity. Any modifications in a procedure must be approved in writing by the laboratory director prior to instituting the change, and the laboratory would then need to abide by all the regulations pertaining to high complexity testing, including personnel requirements and establishment of performance specifications.

WAV 2
Addresses requirements to always follow manufacturer's instructions in the performance and review of QC and to take corrective actions before patient testing.

Is all Quality Control performed per manufacturer's instructions, and are the results of QC recorded, reviewed, and found to be acceptable prior to patient result reporting?

The test system may have both internal and external Quality Control. The results of these controls demonstrate that the test is performing appropriately. These controls must be performed as required by the manufacturer. External QC must be performed at the frequency stated by the manufacturer.

Prior to reporting patient results, testing personnel must:

- Perform all required QC,
- Review QC to ensure it is acceptable, and
- Document that QC is acceptable.

WAV 3
Addresses requirement to document corrective action when QC is out of range.

Do the Quality Control records indicate evidence of corrective action when controls do not give the expected results?

If QC is not acceptable, do not report patient results. Investigate the cause of the QC failure, perform the

necessary corrective action, document the action, and re-run control and patient samples. Do not report patient results until the problem is identified and corrected, and QC results are as expected.

WAV 4
Addresses need for qualified oversight of testing performed.

Are the Quality Control results reviewed monthly by the Laboratory Director or designee?

On a monthly basis the Laboratory Director or designee must document the review of all Quality Control results to assess

- That they are being performed and recorded appropriately,
- That corrective action has been performed to resolve unacceptable QC results, and
- To determine that no patient results were reported when QC was unacceptable.

If patient results were reported when Quality Control was unacceptable, those patients affected must have medical record reviews to determine if further action is indicated. This review should be documented.

WAV 5
Addresses record keeping for quality control.

Are all Quality Control results retained for two years from the date of performance?

All Quality Control results and results of corrective action should be retained for two years.

WAV 6
Addresses need for continuous Competency Assessment to ensure personnel remain competent throughout their career in the laboratory.

Is employee competency assessed and documented prior to initiating testing, at six months during the first year of employment, and annually thereafter?

Each laboratory employee must have competency assessed and documented for each procedure the employee performs. Evaluation of competency should include pre-analytic, analytic and post-analytic phases of testing. This must be done after initial training, six months after initial employment, and annually thereafter. If there is a change in procedure for a given test, or if a new test is introduced into the laboratory, competency assessment must be performed prior to beginning patient testing of the revised or new analyte. All competency results must be retained for two years.

The laboratory must verify that non-laboratory personnel performing waived testing have completed an initial competency assessment prior to testing, a six month evaluation of competency, and annual competency assessments thereafter while they are performing testing. Non-laboratory employees performing only waived testing do not need be listed in the COLA roster of laboratory employees, but the lab is expected to maintain a current, accurate list of all non-laboratory personnel who are performing waived testing.

WAV 7
Addresses need for complete, up-to date, accessible procedure manual for the staff.

Is a complete, up to date and approved procedure manual readily available to all employees performing waived testing?

A procedure manual is not a federal requirement for waived testing; however, federal regulations do require following all manufacturers' instructions when performing waived testing. When appropriate, the package insert may be used as the test procedure. If your laboratory is performing several different tests, it is beneficial to create a procedure manual to organize and maintain the various procedures. This procedure manual could be used for all procedures, including those for pre-analytical activities, safety precautions, etc.

The procedure manual must be signed at least once by the current Laboratory Director. Thereafter, all new and changed procedures must be signed and dated by the Laboratory Director. The manual must be reviewed annually, but this review may be performed by the Lab Director or designee.

When the package insert is used as the procedure, it must be signed and dated by the Laboratory Director prior to initiating patient testing. When new package inserts are received, they should be examined to determine if there have been any changes from prior package inserts. When the package insert is utilized as the procedure, changed package inserts must be reviewed and signed by the Laboratory Director prior to use. If the package insert is not the procedure for the test and the package insert contains

changes, appropriate changes must be indicated in the test procedure in use. The changes must be signed and dated by the Laboratory Director.

WAV 8
Written procedures must include pre-analytic activities.

Are there written procedures for pre-analytic activities, such as patient identification, patient preparation, specimen collection and labeling, and accessioning?

To produce quality, accurate test results, it is essential to:

- Properly identify the patient prior to specimen collection;
- Correctly link the specimen to the patient;
- Process, transport, and store specimens according to manufacturer's instructions;
- Maintain specimen identification throughout all phases of testing.

Developing procedures to address these pre-analytic activities, and ensuring that all personnel follow these procedures will help your lab consistently produce quality test results.

Prior to specimen collection, each patient must be identified by *two* unique identifiers (e.g., name and birthdate). When possible, specimens should, in turn, be labeled with two identifiers. Specimen collection and handling procedures, included with each procedure, must be followed by all staff performing these steps. If a delay in testing or transport occurs, the specified specimen storage/transport procedures for the test need to be followed.

Specimen collection procedures should also address *specimen acceptability criteria*. The practitioner should be informed whenever a specimen is unacceptable for the test ordered, so a decision to re-collect the specimen can be made in a timely fashion.

WAV 9
Results entry and record-retention.

Are all patient results appropriately entered into the medical record in a timely manner, and are the results retained for at least two years?

For every test ordered, a test result needs to be recorded or an explanation provided for the lack of a result. Reports of waived testing results should include the information required in the COLA criteria Post Analytic Section, PST 9-16, 19 and 21. *Report critical values to the ordering practitioner immediately, according to your policy*. Retain records for at least two years. Longer retention times may be necessary depending on the type of record, and local and state requirements.

WAV 10
Proficiency Testing

Is proficiency testing performed for all waived analytes, when available?

Proficiency Testing (PT) is *not* a federal requirement for waived testing; however, its utilization does represent Good Laboratory Practice. PT serves as an external check to verify the accuracy of your laboratory's test results by providing unknown specimens for you to analyze. It is an important aspect of a laboratory's overall assessment of quality. Laboratories gain significant information about their performance as a result of participation in a Proficiency Testing program. Split specimen testing is another option for verifying the accuracy of your waived tests.

<u>In the performance of Proficiency Testing, the following guidelines must be observed:</u>

a. All Proficiency Testing samples should be examined when they arrive in the laboratory. If the samples are of questionable integrity and replacement samples are needed, the PT provider should be notified immediately.

- The cut-off date for submission of results should be noted.
- All Proficiency Testing samples must be treated in the same manner as patient samples.
- Testing of the PT samples must be assigned randomly to the individuals who routinely perform patient testing.

(For further explanation, see annotation for COLA criterion PT 5.)

b. There must not be any communication with any other laboratory regarding PT samples or results prior to the cut-off date for the submission of results.

c. Proficiency Testing samples must not be sent to any other laboratory EVER, even if your laboratory is temporarily unable to test them. The PT provider should be promptly notified of any inability to test the PT samples, so your laboratory will not

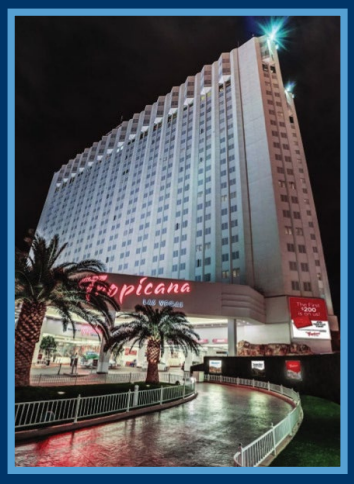
receive an unacceptable score. Do not send PT samples to another laboratory, even if your laboratory normally refers patient samples. If your laboratory would normally refer the sample to another laboratory, this should be documented on the result submission form.

d. All documentation of how the Proficiency Testing samples were handled, prepared, processed, and tested should be retained. Include the booklet provided with the samples by the PT provider, all work sheets, result submission sheets, instrument tapes and logs related to the samples, and the attestation sheet signed by the testing personnel and the Laboratory Director.

e. When Proficiency Testing results are received, they should be evaluated by the Laboratory Director or a qualified designee. The results of the evaluation should be shared with the testing personnel. All unsatisfactory or unsuccessful PT results should be investigated; consultation obtained, where indicated; and remedial education performed, as appropriate. All ungraded results and those not scored should be evaluated. It is recommended that the Laboratory Director review/initial/date all Proficiency Testing reports, but at a minimum, should review/initial/date all investigations of unsatisfactory or unsuccessful PT results.

f. All the Proficiency Testing materials referred to in (d) and (e) above must be retained for two years.

SAVE THE DATE!



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Personalized Medicine – How Does The Lab Fit In?

Introduction

Throughout history, the practice of medicine has largely been reactive. Even today, we usually wait until the onset of diseases and then try to treat or cure them. And because we don't fully understand the genetic and environmental factors that cause major diseases such as cancer, Alzheimer's and diabetes, our efforts to treat them are often imprecise, unpredictable and ineffective.

In addition, the drugs and treatments we devise are tested on broad populations and are prescribed using statistical averages. For example, on average, any given prescription drug now on the market only works for half of those who take it. Among cancer patients, the rate of ineffectiveness jumps to 75 percent. Anti-depressants are effective in only 62 percent of those who take them.[1]

Personalized medicine is beginning to transform the practice of medicine. It is allowing health care providers to:

- Shift the emphasis in medicine to prevention and prediction of disease rather than reaction to it;
- Focus on susceptibility to disease, improve disease detection, preempt disease progression;
- Ability to make more informed medical decisions; earlier disease interventions than was possible in the past;
- Customize disease-prevention strategies;
- Prescribe more effective drugs and avoid prescribing drugs with predictable side effects;
- Have a higher probability of desired outcomes thanks to better targeted therapies;
- Reduce the time, cost, and failure rate of pharmaceutical clinical trials, and
- Eliminate trial-and-error inefficiencies that inflate health care costs and undermine.

What is Personalized Medicine?

Personalized medicine is an evolving field of medicine defined as the tailoring of medical treatment to the individual characteristics, needs and preferences of each patient during all stages of care, including prevention, diagnosis, treatment, and follow up. In a nutshell, personalized medicine can be described as providing "the right patient with the right drug at the right dose at the right time."[2]

This approach relies on understanding how a person's unique molecular and genetic profile makes them susceptible to certain diseases. Scientists advanced the cause of personalized medicine with the decoding of the human genome, a genetic map of the body. They identified 20,000-25,000 human genes and the sequences of billions of chemical pairings within DNA—the building block of our genetic makeup.

While personalized medicine is the antithesis of the "one size fits all" treatment protocols available for treating disease, it can, at the same time,be considered as parallel to the traditional approach in the treatment of disease but using more precise tools.

Personalized medicine is also about[3]

- **Risk Assessment**: genetic testing to reveal predisposition to disease.
- **Prevention**: Behavioral/lifestyle/Treatment intervention to prevent disease.
- **Detection**: Early detection of disease at the molecular level.
- **Diagnosis**: Accurate disease diagnosis enabling effective disease strategy.
- **Treatment**: Improved outcomes through targeted treatments and reduced side effects.
- **Management**: Active monitoring of treatment response and disease progression.

The Promise of Personalized Medicine

In 2003, after more than a decade of research, the Human Genome Project was completed by the U.S. Department of Energy and the National Institutes of Health.

The goals of the Human Genome Project were to learn the order of the 3 billion units of DNA that go into making a human genome, as well as to identify all of the genes located in this vast amount of data. By 2003, almost all of the pairs of chemicals that make up the units had been put in the correct sequence—enough for a pronouncement of success. The individual genes within the long strands of DNA, and the elements that control the genes, are still in

the process of being identified. Current counts indicate that the human genome contains 22,000 to 23,000 genes.

One of the early hopes of the genomic project was to pinpoint specific genes that caused common diseases. Scientists now think the answer is more complex, with many diseases the result of multiple genes interacting.

With the knowledge an individual's genome influences his or her likelihood of developing (or not developing) a broad range of medical conditions, personalized medicine also focuses strongly on wellness and disease prevention.

For example, if a person's genomic information indicates a higher-than-average risk of developing diabetes or a particular form of cancer, that person may choose a lifestyle, or sometimes be prescribed medications, to better regulate the aspects of health and wellness over which he or she has control. The person may benefit in the long run from making preventive lifestyle choices that will help counteract the biological risk.[4]

Genomic medicine may help determine a person's risk of developing several specific medical conditions, including:

- Cancer
- Cardiovascular disease
- Neurodegenerative diseases
- Diabetes
- Obesity
- Neuropsychiatric disorders

Researchers are actively investigating the genomic and genetic mechanisms behind—and developing predictive testing for—such diverse medical conditions as:

- Infectious diseases, from HIV/AIDS to the common cold
- Ovarian cancer
- Cardiovascular disease
- Diabetes
- Metabolic abnormalities
- Neuropsychiatric conditions, such as epilepsy
- Adverse drug reactions
- Environmental exposure to toxins

Companion Diagnostics: Key Components of Personalized Medicine

Stephen P. Spielberg, M.D., Ph.D., FDA's deputy commissioner for medical products and tobacco said the challenge in developing new drugs is "recognizing the huge human diversity in the causes of disease and in the response to medicines and other interventions. It's figuring out the true biological basis of diseases, increasing diagnostic precision, and developing and using medicines targeted at specific causes of disease."[5]

An aspect of this is pharmacogenomics, which uses an individual's genome to provide a more informed and tailored drug prescription.

Companion diagnostics are tests that help determine whether a patient should receive a particular drug therapy or how much of the drug to give, tailored specifically to the patient, said Elizabeth A. Mansfield, Ph.D., Deputy Office Director for Personalized Medicine in FDA's office of In Vitro Diagnostics and Radiological Health.

Because the companion diagnostic test is designed to be paired with a specific drug, the development of both products requires close collaboration between experts in both FDA's device center, which evaluates the test to determine whether it may be cleared or approved, and FDA's drug center, which evaluates the drug to determine whether it may be approved.[6]

The Role of The Laboratory

Since advances resulting from the sequencing of the human genome have made it possible to detect disease at earlier stages, new gene-based and other molecular diagnostic laboratory tests have been developed that can identify a person's susceptibility to disease before symptoms occur.

An example is genetic testing for BRCA1 and BRCA2 mutations that can indicate individual risk for developing breast or ovarian cancer.

New gene-based and other molecular diagnostic laboratory tests can also be used to determine the benefits and harms for an individual of taking certain medications. These tests are known as *companion diagnostics*. Information on an individual's drug metabolism, for example, can yield information on who might benefit most from a drug and those at risk for atypical adverse reactions (through genetic variations influencing the rate and efficacy of drug metabolism, or other genetic variations related to drug response). Tests can also inform the optimal dose or treatment frequency needed to achieve a desired therapeutic effect in an individual patient. Examples are:

- HER2/neu testing to guide the prescription of the cancer drug Herceptin for breast cancer.

- UGT1A1 testing to guide the dosage of the chemotherapy drug irinotecan for metastatic colectoral cancer.[7]

Predicting Beneficial and Adverse Treatment Effects[8]

Over the past decade, molecular diagnostics (MDx) have ignited a surge of interest in the power of personalized medicine. The first wave of MDx tests was for treating infectious disease; now cancer is the new frontier. Laboratories are actively evaluating expanded test menus, including genomic tests combined with traditional cancer diagnostics for more personalized cancer treatment.

Three Challenges

There are three challenges that laboratories will need to address to successfully integrate traditional and genomic-based early cancer detection tests into their offering.

1. Personalize Screening and Assessment Guidelines for Patients at Higher Risk of Cancer

A study of physicians' medical records for 741 patients, published by the Journal of the *American Board of Family Medicine*,[1] noted that detailed family history information was insufficient to permit cancer risk assessment in more than two-thirds of patients. Individuals at moderate or high cancer risk were not identified as such in these medical records. The study concluded that family physicians need to adopt explicit risk assessment criteria to identify, and to optimally care for, those at increased risk for cancer.

Laboratories can play an important role in supporting physicians in these risk assessment efforts. Panels of traditional tests and key clinical data can be offered to build a cancer risk profile that is easy for physicians to understand and explain to their patients. Patients who have been identified as being at a higher risk of cancer are clearly candidates for genomic-based blood tests prior to invasive biopsies or surgery. This new protocol can both reduce costs as well as improve quality of care.

"The future lab will play a much stronger role in identifying and staging cancer, which means labs will be more involved with interpretation and results reporting," said Heiner Dreismann, former president and CEO of Roche Molecular Systems. "This shift will not only change the role of the lab, but empower them to play a more vital role in healthcare outcomes than ever before. Labs must think beyond individual assays due to the heterogeneous nature of the over 2,000 types of cancer that have now been identified. Each type of cancer demands unique panels of assays."

2. Labs Add Value to Physician Practices Through Education

A major shift on the horizon is that personalized cancer care will begin in the primary care physician's office, not with cancer specialists. In addition to ordering traditional cancer diagnostic tests, primary care physicians (PCPs) will be ordering genomic-based tests that they are far less familiar with. Laboratories can add value to the physician's practice through education to physicians, nurse practitioners and physician assistants to:

1. Identify patients and their families at increased risk for cancer and how to personalize cancer screening and assessment guidelines.

2. Explain the clinical utility of new genomic-based tests and how they can help the PCP identify patients at higher risk of cancer.

3. Explain non-invasive alternatives to biopsy procedures that pose their own risks of infection and complications.

4. Allow PCPs to play a role in active surveillance now dominated by cancer specialists who may bring a bias toward aggressive treatment for all cancers.

3. Laboratories as Clinical Consultants

One of the biggest changes facing laboratories in the future will be shifting the lab's role from clinical service to clinical consultant. Most of the genomic tests for cancer require interpretation. The real value of the new genomic test menus can only be achieved by influencing the management of patients and related clinical outcomes. Thus, lab managers will need to join the healthcare delivery team and play a role in patient management. The challenges that labs will face in offering panels of new tests for early cancer detection are many. New offerings will likely affect every function of the lab, including staffing, processing, equipment purchases, results reporting, billing, validation and continuous education and training. While developing test menus, labs will not only have to evaluate pricing and ROI, but they also will require more staff and new skill sets for interpreting test results and reporting results beyond entering results into lab information systems.

As well, labs will need to stay up to date with the latest advances in these technologies and their applications. Next-generation sequencing (NGS), for example, has been quickly adopted by major academic medical centers, but reimbursement reality is still limiting its acceptance in community healthcare systems. It is only a matter of time before labs will need to integrate NGS diagnostic tests as well.

Personalized Medicine and the Laboratory: Obstacles To Overcome

Methodological and logistical challenges in validating apparent correlations between genetic markers and disease.

Regulatory and reimbursement systems that were not designed to accommodate complex genomics-based diagnostics.

Absence of the electronic medical record-linked decision support tools needed to integrate the results of genomics-based diagnostic tests into routine clinical practice.

Intellectual property laws and practices that may present barriers to investment in genomics-based diagnostics.

Privacy concerns that may limit patient acceptance of genomics-based diagnostics.

Education of patients and physicians on the proper use and limitations of new genomics-based diagnostics.

RESOURCES:

The Jackson Laboratory: Genetics and Your Health/ Personalized Medicine and You. 2014. http://geneticheath.jax.org/personalized-medicine/what-is/benefits.html

1. FDA: U.S. Food and Drug Administration. Personalized Medicine: FDA's Unique Role and Responsibilities in Personalized Medicine. http://www.fda.gov/ScienceResearch/SpecialTopics/PersonalizedMedicine/default.htm
2. The Age of Personalized Medicine. Personalized Medicine Coalition (PMC). "What Is Personalized Medicine". 2011 http://ageofpersonalizedmedicine.org/what_is_personalized_medicine/
3. USNews/Duke Medicine: Overview of Personalized Medicine 2011. http://health.usnews.com/health-conditions/cancer/personalized-medicine/overview
4. FDA; U.S.Food and Drug Administration: Consumer Updates: Personalized Medicine Will Fit You Like A Glove. http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm317362.htm
5. FDA; U.S.Food and Drug Administration: Consumer Updates: Personalized Medicine and Companion Diagnostics Go hand-In-Hand. http://www.drugs.com/fda-consumer/personalized-medicine-and-companion-diagnostics-go-hand-in-hand-318.html
6. ADx/AdvaMedDx: A Policy Primer on Diagnostics, June 2011 Pp.14-18. http://advameddx.org/download/files/sections/Policy/Innovation/AdvaMedDx-Policy-Primer-on-Diagnostics-June-2011.pdf
7. Advance For Laboratory Professionals: reprint of Personalized Medicine: "How Labs Must Prepare for Genomic-based Tests For Cancer" by Karl Wasserman, Executive vice president, U.S. Corporate Development, GeneNews. http://laboratory-manager.advanceweb.com/Archives/Article-Archives/Personalized-Medicine.aspx

Waived Testing and Patient Safety[1]

Laboratory testing plays a critical role in health assessment, treatment, monitoring, and ultimately, the public's health. Test results contribute to diagnosis and prognosis 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. An estimated 7-10 billion laboratory tests are performed each year in the United States, and laboratory test results influence approximately 70% of medical decisions.

The Spread of Waived Testing

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.

Advances in technology have made tests simpler and more robust, and this has contributed significantly to the shift in testing from the more complex tests to the simpler waived methods. In the past, tests such as cholesterol and glucose used complex manual methodologies or 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. Point-of-care testing (POCT) is the leading edge of decentralized laboratory testing. More recently, POCT has taken place in war zones, rural areas in nations that lack adequate healthcare facilities; and at loci of infectious disease outbreaks. A recent example is the use of POCT in villages experiencing the Ebola epidemic.

Waived Testing: An Indicator of Change

When we think of waived testing, we tend to think of it as one of three categories of test complexity defined by CLIA. However, it is really more than that; it is both a driver and a product of two separate forces radically affecting healthcare delivery in general, and laboratory medicine in particular: technology and the increasing decentralization of the laboratory, and the movement toward patient centered care and personalized medicine. The key fact is that waived testing is a significant component of POC testing.

Technology

The worldwide spread of mobile/smart phones has allowed developing countries to leap over the landline phase of telephone construction, and accelerate the development of phone and internet communications, and compress 50 years of development into five years, with the resultant acceleration of their economies. In the same manner, the development of portable, simple, accurate and rapid laboratory testing has allowed developing countries to more rapidly apply the use of laboratory testing for the diagnosis, treatment and monitoring disease , accelerating the development of their healthcare systems, and improving the lives of their citizens. They were able to compensate in part, their lack of transportation, communication and brick and mortar healthcare infrastructure, such as large centralized laboratories.

Not All Is Rosy

However, as easy to use and reliable as these waived test systems are, serious quality concerns have arisen over the years. Study after study, first by CMS, then by the CDC and state health agencies, have indicated that laboratories with Certificates of Waiver have higher percentages of quality problems. Those conducting these studies have concluded that most of these problems can be attributed to the lack of required standards for personnel qualification, training and competency assessment. Problems in

these areas are the progenitor of problems in oversight, accountability, quality control, quality assessment, and documentation. These issues affect all phases of laboratory testing, including pre-and post-analytical.

If we are to continue to benefit from advances in laboratory technology, then these issues will have to be resolved first. Quality patient care first!

There is a consensus in the communities of laboratory professionals that CMS will eventually take steps to institute specific requirements to address these issues; an accreditation program for waived testing that may include required:

- Personnel qualifications, adequate training, and competency assessment
- Proficiency testing
- Continuing education in Good Laboratory Practices
- Proper documentation of quality control, test results, reagent expiration dates.
- Written procedure manual
- Random on-site visits

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 Resources, Inc (CRI), the educational subsidiary 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, CRI 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.

RESOURCES:

1. 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.

inSights SPOTLIGHT:
LABORATORY EXCELLENCE AWARD

The lab at Internal Medicine has been accredited by COLA for over 20 years and has earned the laboratory excellence award three times. We are so excited to be featured in the SPOTLIGHT! It emphasizes our commitment to laboratory excellence, from patient care to test results.

Originally an independently owned physician office practice, we are now owned by LifePoint Hospitals. The practice currently has seven providers whose specialties include Internal Medicine, Family Medicine, Infectious Disease and Gastroenterology.

INTERNAL MEDICINE ASSOCIATES

Danville, VA

Laboratory Director:
Andrea Adkins, BS, ASCP

Medical Laboratory Technicians:
Tina Brower, AS, ASCP
Jill McBride, AS, ASCP

Phlebotomists:
Melissa Martin
Jennifer Jamison

Our lab's mission statement is the same as LifePoint Hospital's, we CARE!

The Customer is Always First
Actions Speak Louder than Words
Respect is the Golden Rule
Excellence is Our Standard

Our dedicated laboratory staff includes a lab director, two medical laboratory technicians, two phlebotomists and a clinical consultant. Two of our lab employees have been employees at Internal Medicine for almost 20 years, one other has been here 10 plus years and the other two almost 5 years!

Those in the laboratory world know that lab work is a behind the scenes job, we are not seen thus often forgotten about. Over the years, I have heard lab employees say, "I feel no one really knows what I do every day. People think I come in, draw blood, put tubes on the instruments, accept results and that is it. People need to realize it is so much more to it than that!"

Working in a physician office lab allows us to have patient contact. Each of us thrives on that and feels fortunate to have relationships with our patients. Based on our practices' work flow, lab employees are often the first clinical faces that patients see and our goal is to make each patient feel cared for, special, and appreciated.

My goal as lab director is to include each laboratory employee, from phlebotomist to lab tech, in the process of total patient care. All employees are equally important! Every month, as part of our Quality Assurance Program, a specific topic is chosen and we discuss what we are currently doing and can we improve it? Our lab is accredited in Mycology, Parasitology, Routine Chemistry, Urinalysis, Endocrinology and Hematology so I choose topics that relate to each of these areas. In addition, one section from COLA's self-assessment questions is discussed and the lab technicians are quizzed to ensure full understanding of each assessment. Furthermore, we take Quality Assurance one step further by checking technical competencies and utilizing COLA's Quality Assurance program book along with COLA Central.

In the future, we hope to see laboratory employees gain the same recognition by society as nurses, doctors and other healthcare workers. Thanks to organizations such as COLA this may one day be a reality!