

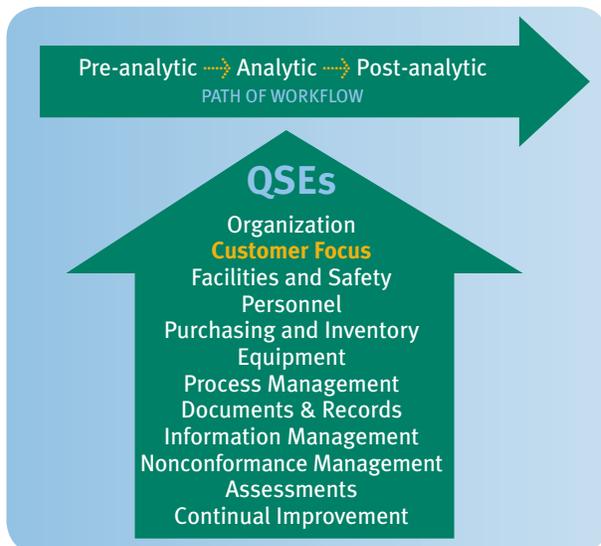
NOVEMBER / DECEMBER '10

INSIGHTS

INSIGHT INTO QMS QSE CUSTOMER FOCUS

Quality Management Systems (QMS) is a systematic approach to quality management with a focus on error prevention and efficiency. Its goal is to take quality and effectiveness to a higher level of performance. The QMS is divided into 12 components or Quality System Essentials (QSEs). The QSEs work together to comprise a quality management system that supports the path of workflow and forms the foundation of the laboratory's operations.

As described in the upcoming release of the 4th edition of the CLSI guideline *Quality Management System: A Model for Laboratory Services*, the order and some of the names of the QSEs have changed. The revised model below shows these changes.



QSE Customer Focus (formerly called QSE: Customer Service) is about why your laboratory needs to identify:

- its external and internal customers
- their expectations, and
- their perception of your services.

To be successful, quality management must focus on the customer. A customer is any individual or group that receives the service, work product, or output of your processes. The customer has expectations of your laboratory processes that need to be met.

Identifying your laboratory's customers is essential because your laboratory's entire path of workflow needs to be designed to fulfill customer requirements and expectations. Once you have identified your external and internal customers, it is important to determine what they expect from you. Staff members need to cooperate with other staff members (internal customers) so that the best service is provided to external customers.

It is important to design your laboratory's path of workflow processes to fulfill the expectations of both your internal and external customers. Processes that are not meeting customer expectations should be redesigned to do so.

Develop a program for collecting and analyzing customer perceptions of your services and for communicating the results to management for action.

1. Gather feedback using a combination of reactive and proactive methods.
2. Analyze the information gathered.
3. Present the analyzed information to those who can take action on it.

Sometimes organizations conduct surveys but then fail to integrate the results into their continuous improvement and strategic planning processes. Your laboratory needs to include the feedback in your periodic quality report (quality reports are discussed in **QSE Assessments**) and act on it.

Laboratory management should review customer feedback and ask "Which processes need to be fixed to remove customer dissatisfactions?" Processes that need corrective action should be referred to the appropriate staff to address process improvement. More information can be found in **QSE Continual Improvement**, which discusses how to resolve process problems.

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FROM THE CHAIR

It is only fitting that the last printed issue of Insights is "Customer Focused" since you, our customers, are the driving force at COLA. We have you in mind when we make business decisions, survey and evaluate your laboratories, launch new educational products, and select Symposium speakers. We value your input and strive to listen to and follow-up on your comments and suggestions.

"Customer Focus" is also the new name of the Customer Service QSE, based on new CLSI guidelines. This QSE is highlighted in the cover article.

The new column "Surveyor Spotlight" will focus on issues and items that our surveyors bring to our attention. For example, if they see that several laboratory professionals are having trouble complying with a particular COLA criterion, we'll highlight it in this column. The inaugural piece addresses a QC standard that recently seems to be causing problems in several laboratories.

In the previous *Insights* issue, we published a letter from the CDC, which has since generated several customer questions. The CDC addressed these and supplied a FAQ document that is included in this *Insights* issue.

We always love to hear from you and thought you might like to see what other customers are saying. We decided to share some of your latest comments in the last article in this issue. It lists just a few of the comments we received from those of you who attended our last Symposium.

We have numerous new ideas for the electronic version of *Insights*, many of which could not be implemented in a printed version. Join us in the New Year to see what's in store!

Verlin K. Janzen, MD, FAAFP
 Chair, COLA Board of Directors

INSIGHT INTO QMS, QSE CUSTOMER FOCUS continued from page 1

In summary, Customer Focus is about:

- Delivering what the customer wanted
- Caring about the customer's wellbeing and their perceptions of:
 - Your services
 - Your people
 - Your reputation

High quality testing and services can only result from satisfied internal customers serving satisfied external customers!

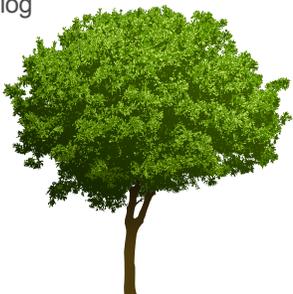
Note: The Quality Management Systems (QMS) courses on LabUniversity® are currently being revised to correspond with the release of the revised CLSI document on which they are based. We will keep you informed about when these revised courses will be available.

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To view recent issues of Insights, log in to COLAcentral.com and click on the Education/Resources tab, then Insights Newsletter.

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SURVEYOR SPOTLIGHT

Quality Control: New Lot Number Verification

Our surveyors have noticed that many laboratory professionals are having problems understanding COLA criteria question QC #8, which states, "Are the materials used as controls verified by repetitive testing to meet the manufacturer's established parameters for mean and standard deviation?" We want to help clarify what this means and provide you with the help needed to comply with the criterion. However, it is not applicable to test systems where the controls, standards, and reagents come packaged together as a unit to be used together with no interchanging of materials among kits or lot numbers.

For non-waived quantitative analytes, new lot numbers of assayed controls need to be verified prior to use. Since the controls are assayed, the manufacturer has established expected result ranges for the controls. You need to confirm (or verify) that the controls will fall within these established ranges when they are used on your lab's analyzer. This verification is to be performed before the old (current) lot number is depleted.

The following procedure, for assayed controls, should provide guidance in complying with this criterion. Un-assayed controls fall under QC #9, which is discussed at the end of this article.

Note: If the manufacturer has specific procedures or requirements for verification, they must be followed. For example, Cell Dyn 1700 has an Assay Verification procedure located in the manufacturer's operators' manual. Some manufacturers of assayed controls may indicate in the package insert that the laboratory establish its own means and acceptable ranges and use the ranges provided for guidelines only. Other manufacturers may provide a range of means. In either of these instances, it is up to your laboratory to establish your own QC range, ensuring that your mean falls within the range of means provided by the manufacturer.

Procedure: Quality Control: New Lot Number Verification

1. Run daily QC, i.e. test the current (old) lot number and make sure it is within its acceptable range.

While the current (old) lot number is in use, run the new lot number of controls five times.** Generally, five values are considered adequate to verify a range when performing parallel testing, but less may be used if the laboratory can justify this. Please call COLA if you have questions about using less than five values.

- a. It is preferable to do this over five days, using more than one operator.
- b. Ensure that the control is well mixed prior to use. Testing a sample from an inadequately mixed control

will not only give an inaccurate QC result, but will also compromise the remaining control in the vial.

- c. The new lot can be run as a patient or in a different QC file, if the instrument has multiple QC file capability.
 - d. Verify new lot numbers for all levels of controls to be used.
2. Compare the results of the new control with the manufacturer's expected control range for the new lot number.
 - a. If the new control results are within the manufacturer's established range, the new lot number has been verified. It can be put into use when the current (old) lot number of control is depleted.
 - b. For documentation purposes, attach the QC verification data to the QC package insert. Have your lab director (or designee) sign and date the data as approval of the verification. Indicate the date when the new lot number is put into use on the verification form or the QC package insert. Keep verification data and the QC package insert for two years.
 3. If the new control results are outside of the manufacturer's range, actions need to be taken to determine why the control is not performing as expected.
 - a. Verify that the new lot number has not expired. If it is expired, notify the supplier and request a new shipment of controls.
 - b. Mix the controls well and rerun them. If the values are within range, continue with Step #2.
 - c. If controls are still out of range, notify the lab director or supervisor that you are having problems verifying the new lot number of controls.
 - d. Verify the condition of the controls when shipment was received.
 - Was it properly shipped?
 - Were the controls warm?
 - Notify supplier if there are any problems with the condition of the controls when received. They may need to send a new shipment of controls.
 - e. Ensure that you are using the correct QC package insert.
 - Are the correct manufacturer's ranges being used? Are they actually for the lot number being verified?
 - Are you using the established ranges for the correct analyzer?
 - Has the information been correctly entered in the instrument / LIS?

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QUALITY CONTROL: NEW LOT NUMBER VERIFICATION *continued from page 3*

- f. Open a new vial of controls and rerun QC.
 - If QC now falls within range, continue the verification process. (Go back to Step #2.)
 - Notify supplier that you had a bad set of controls and request a replacement set.
 - If QC does not fall within the manufacturer's range, there could be a problem with the lot number or the analyzer. (Proceed to Step #3-g.)
 - g. Verify the status of the current (old) lot number of controls.
 - Review the Levey-Jennings (QC) graphs. Are there any shifts or trends occurring? If yes, the instrument may need to be calibrated.
 - h. Check the date of the last calibration.
 - If due, then calibrate.
 - If not, review the data from the last calibration. You may need to talk with the analyzer's technical support for assistance.
 - i. Make sure all required maintenance has been performed.
 - j. If no problems are found with the analyzer, contact the quality control manufacturer or supplier for assistance. They may be aware of laboratories that are having similar problems or they may need to send replacement controls. This could mean sending another new lot number. If the different lot number does not work, you might want to try another company that makes controls for the tests you are performing. Running QC from a different manufacturer may help in determining if the problem is with your analyzer or the controls.
 - k. When problems are resolved, continue verifying the new lot number, beginning with Step #1.
4. Document all corrective actions taken and communications with supplier or technical support, if applicable. Maintain documentation with QC records for two years.

****Note:** *If the shipment with the new lot number of controls does not arrive in time to run the verification over five days, run the verification over the number of days available. Regardless of the number of days, we recommend that you use five points for each level of control to be verified. If the shipment arrives after the old lot number has expired, run the new lot number of controls five times over the course of the day, then follow the rest of the verification steps described in the procedure. Make a notation that the controls did not arrive in time to perform the five day verification procedure. For Quality Assessment (QA), monitor future shipments for possible problems with the supplier. Take action as described in your QA plan.*

COLA criteria question QC #9: *If you use un-assayed controls, do you establish control values by doing concurrent testing with samples of known values?*

If the controls you are using are un-assayed, they do not have ranges established by the manufacturer. Therefore, you need to establish your own ranges by running the controls on your analyzer and determining the means and standard deviations (SD). Acceptable ranges usually run from the mean minus 2SD to the mean plus 2SD (mean \pm 2SD). Means and SDs should be established on no less than 20 values. This can be done over 20 days or multiple runs on a few days (e.g. five runs of each level performed for four days).

QUESTIONS AND ANSWERS FOR LABORATORY DIRECTORS AND LABORATORY SCIENTISTS REPORTING RESULTS OF GC/CT NAAT TESTS

There have been inquiries following the distribution of the CDC "Dear Colleague" letter of August 18, 2010. (Note: This letter was published in the Sep/Oct issue of Insights.) The following questions and answers have been formulated by CDC to share with all interested parties, and were developed in consultation with APHL, FDA, and CMS.

Q: What were the specific concerns addressed by the CDC Dear Colleague letter?

The August 18, 2010 letter from Dr. Fenton, Director of CDC's National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention, to laboratory directors addressed CDC concerns that arose from knowledge that some laboratories are routinely retesting positive specimens that are close to the positive cutoff (i.e., low positive) on commercially available chlamydia and gonorrhea nucleic acid amplification tests (NAATs) and reporting them as

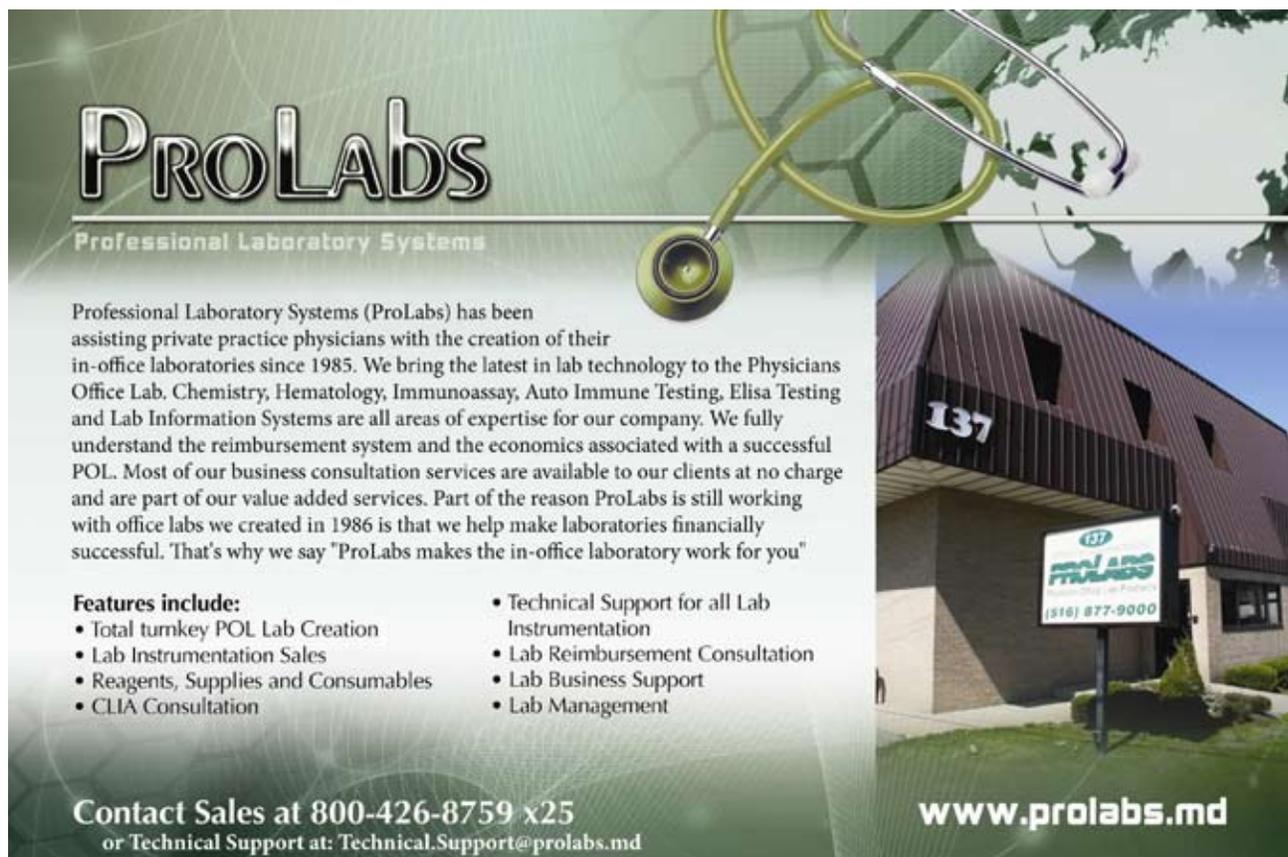
negative if the repeat test is found to be negative. The intent of the advisory was to clarify how laboratories should report test results, rather than laboratories' testing procedures. This concern relates only to those laboratories that are not following manufacturer instructions and have not validated their changes to the instructions.

The letter requested that Laboratory Directors review their procedures and affirm appropriate diagnostic results by following manufacturers' instructions or using verified modifications to the product insert. The letter was not intended to circumvent Laboratory Directors' professional judgment when repeat testing is performed as a result of suspicion that a run was not valid, or when discrepant test results are reported as "indeterminate," "equivocal," "inconclusive," or a similar reporting terminology that indicates doubt about interpretation.

Q: How should laboratories report discrepant results from routinely retested specimens?

In the event of discrepancy in results when specimens are retested, both results should be reported to the clinician who ordered the test, along with an overall

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QUESTIONS AND ANSWERS FOR LABORATORY DIRECTORS AND LABORATORY SCIENTISTS
REPORTING RESULTS OF GC/CT NAAT TESTS *continued from page 5*

interpretation of "indeterminate" or "equivocal". This would allow a clinical decision to be made to either treat the index case and to inform partner(s); or to obtain a second specimen for testing, depending on such factors as individual risk and local population prevalence. This approach is a minor clarification of the most recent guidance provided by CDC in the 2002 document "Screening Tests to Detect Chlamydia trachomatis and Neisseria gonorrhoeae Infections"¹ namely:

"... All positive screening tests should be considered presumptive evidence of infection ... When additional testing has been performed, the laboratory should report the results of both the screening test and the additional tests, as well as the overall interpretation (sic 'of "indeterminate" or "equivocal"). The laboratory has the responsibility to educate clinicians regarding the importance of all laboratory results, including both screening and additional test results. In particular, clinicians need to be aware of the limitations of the additional tests, including the possibility that they yield false-negative results when the screening test is positive. Because serious side effects from therapies for C. trachomatis and N. gonorrhoeae are uncommon, clinicians might recommend treatment after a positive screening test for a person at risk for infection, pending additional testing or even when a positive screening test is not verified by additional testing."

Q: Does the CDC believe that the performance characteristics of NAATs for GC/CT are suboptimal?

No, this specific concern relates to how the test results are interpreted and reported and not the quality and accuracy of the FDA-cleared, commercially available diagnostic tests. CDC believes that NAATs are the most sensitive and specific tests available for the detection of *C. trachomatis* and *N. gonorrhoeae* infections and has actively promoted the use of these tests in screening for these infections – particularly in young, sexually active women to prevent the sequelae caused by these organisms – namely pelvic inflammatory disease (which is frequently asymptomatic) and tubal infertility.

Q: Why isn't CDC more concerned about the potential for false positive results with these tests?

Routinely retesting low-positive specimens may reduce false positives, but reporting them as 'negative' if the retest result is negative will increase false negatives. Clearly, 'false positive' results can cause undue patient anxiety and disruption to close relationships. However, false negative tests will result in failure to treat infections that could progress to serious health problems such as asymptomatic PID and infertility and allow further spread of these infections. Only by accurately following the manufacturer's instructions in FDA-cleared assays or by using documented performance data or other verified diagnostic algorithm, can the appropriate

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QUESTIONS AND ANSWERS FOR LABORATORY DIRECTORS AND LABORATORY SCIENTISTS
REPORTING RESULTS OF GC/CT NAAT TESTS *continued from page 6*

balance of test accuracy and predictive value be best achieved. NAATs provide qualitative results and their respective signal values cannot be used to judge organism load. Therefore, positive test results close to the positive cutoff of the assay cannot be assumed to be a low-grade infection that will spontaneously clear any more frequently than any other positive result.

Q: Why is CDC recommending that health-care providers be notified of test results that could have been misinterpreted during the past 2 years?

The recommendation applies only to laboratories that modified manufacturers' instructions for retesting specimens and did not complete a verification study for the modified procedure. The recommendation to go back two years is based on two studies. In one, approximately 18% of asymptomatic women with untreated chlamydial infection remained infected two years later.² The other demonstrated that treatment can prevent PID; 7 of 74 women with untreated chlamydial infection (9.5%) developed symptomatic PID in the year following detection of the infection.³ In a recently documented two year lookback study after repeat *C. trachomatis* testing was done and

discordant results were reported as negative, 5 of 49 persons notified and subsequently retested were positive for *C. trachomatis* (recognizing some may have acquired new infections).⁴ Therefore, it is imperative for laboratorians to inform clinicians who can reach patients, offer them an opportunity to be retested and for those who may be unknowingly infected with Chlamydia, give them treatment that can ultimately cure the infection and prevent serious related health consequences.

Q: When will CDC update the 2002 screening guidelines with more specific information on chlamydia and gonorrhea testing procedures?

In January 2009, a consultation was held to discuss recommendations for updated guidance. New CDC Laboratory Guidelines for the Laboratory Diagnosis of Sexually Transmitted Diseases are currently being drafted, and we plan to publish these guidelines in early 2011.

If you have any questions or comments, please contact Tom Peterman, MD, MSc, Acting Chief, Epidemiology and Surveillance Branch, Division of STD Prevention, CDC via e-mail (tap1@cdc.gov) or telephone (404-639-6102).

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SYMPOSIUM COMMENTS

We love hearing from you! These are just a few comments we received about our most recent Symposium, held at the Talking Stick Resort in Scottsdale, AZ from Sep 29 through Oct 2, 2010. Our next Symposium is scheduled for National Medical Laboratory Professionals Week (Apr 27 – 30, 2010) at the Hyatt Regency in Atlanta, GA. We'll update the website (www.COLA.org) as more information becomes available.

- As a new lab director, this information is new to me. It was eye opening and will serve as the jumping off point to making sure our small lab is in compliance.
- That was a great conference. I have been to many of these and this was really informative compared to others that really don't have any substance.
- This is my first COLA symposium and I am glad to have attended the event. Excellent program content and speaker line-up. Great hotel location and facilities. Very organized event and hopefully, future sessions will be taped.
- Loved the Empowerment breakout session. Just a great topic for MTs who get little to no positive feedback on job performance. Taught me how to look within for self praise and how to be a positive role model in the lab. Learned a lot about compliance in the COLA Top 10 Citations breakout, too!



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