Ensuring Compliance

When Adding a Specialty or Subspecialty

INTRODUCTION

As you expand the services offered by your laboratory, you'll want to ensure your process for adding tests assures accurate and reliable results and meets accreditation requirements. This can present a challenge if you are adding testing in a new specialty or subspecialty, or if the addition causes a change in the complexity of your laboratory, as there are likely to be new, unfamiliar requirements.

The CLIA requirements and COLA Criteria for Quality Laboratory Performance have general criteria that apply to all non-waived testing and additional specialty and subspecialty specific requirements.

Ensuring you meet all requirements is critical as you expand your services since laboratory reimbursement is tied to COLA's determination of your compliance at the subspecialty level.

The process described in this LabGuide represents good laboratory practice, and it should be followed by any laboratory expanding their test menu to ensure successful implementation. As an extra measure of quality, it is also recommended for laboratories implementing new waived procedures.

WHAT ARE THE LABORATORY SPECIALTIES AND SUBSPECIALTIES?

See Appendix 1 for a listing of specialties, subspecialties, and sample tests.

RESPONSIBILITIES ASSOCIATED WITH EXPANDING SERVICES

Both the laboratory and COLA (as the accrediting body) have specific responsibilities that must be fulfilled when adding tests that expand the laboratory's menu into a new specialty or subspecialty. It is important to recognize these responsibilities and timelines to ensure:

1) The laboratory is competent to provide accurate and reliable results.
2) Appropriate notifications are made, so the laboratory will be eligible for reimbursement.

Note: The responsibilities for the laboratory, shown in Appendix 2, apply whenever testing is added, even if it does not involve the addition of a new specialty or subspecialty.

Prior to performing and reporting patient testing, the laboratory must demonstrate that the new test method performs at an acceptable level when performed by the staff of the laboratory in their own facility. The laboratory must develop a training program for employees and ensure initial competency of those authorized to perform testing. The laboratory should complete a Self-Assessment to ensure that all requirements for accreditation are met. Specific guidance in these areas is provided later in this LabGuide.

The laboratory must communicate with COLA throughout the process. As the accrediting body, COLA is responsible for making an interim assessment of compliance for the new specialty or subspecialty. In most cases, this can be conducted through documentation of the implementation process outlined in this LabGuide, using the form provided (Appendix 3), along with a focused Self-Assessment process. In special circumstances, COLA can require the laboratory to undergo an onsite survey based on the laboratory's accreditation history. An onsite survey is a requirement for laboratories located in the State of Florida that are adding a specialty or subspecialty.

Following successful completion of a Self-Assessment or an onsite survey, COLA will notify the Centers for Medicare and Medicaid Services (CMS) of accreditation in the new specialty or subspecialty. Following this notification, the laboratory's CLIA certificate will be updated, and from this time forward, the laboratory will be eligible to bill and receive reimbursement for the newly added laboratory testing.

The table in Appendix 2 highlights key responsibilities when testing is added. The laboratory must meet these

responsibilities and document they have been met using the Implementation Form (Appendix 3).

Laboratories are expected to complete the Implementation Form each time a new specialty or subspecialty is added and submit it to COLA. To complete the form:

1) Photocopy the form so you can keep the original as your master copy.
2) Complete the form, make a copy, and send the copy to COLA.
3) Keep your original copy and all the associated documents in a file for review by the surveyor at your next onsite survey.

The remainder of this LabGuide offers guidance and references for implementing new testing to assist you in maintaining compliance in laboratory areas essential to the production of accurate and reliable testing.

LABORATORY IMPLEMENTATION PLAN

Complexity & Personnel

Laboratories must first determine the complexity of their new test system and confirm that the corresponding personnel qualifications are met. The manufacturer of your new test system or kit should be able to tell you the complexity of each test on the new test system. You can confirm the complexity by using the FDA web site. The link to that web site is http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfclia/testswaived.cfm.

Use this link to do a search on either the analyte name or test system. Be advised that the web site defaults to an advanced search that requires an exact match between your entry and the database listing. There are options provided to use a drop down list to make entry selections. Clicking on "Go to Simple Search" will permit you to search on a piece of information and does not require an exact match to return results.

Once you have confirmed the complexity of your new test, check the corresponding personnel requirements for each position in the laboratory. The table in Figure 1 identifies the positions required for moderate and high complexity testing.

Figure 1: Positions Required for Moderate and High Complexity

Moderate Complexity	High Complexity
Laboratory Director	Laboratory Director
Clinical Consultant	Clinical Consultant
Technical Consultant	Technical Consultant
	General Supervisor
Testing Personnel	Testing Personnel

To qualify to hold a given position, each individual must meet specific requirements for education and experience. Refer to the Personnel Qualification table in *LabGuide 4: Personnel*.

Use Figure 2 to identify the scenario applicable to your laboratory and the steps to take regarding personnel.

Proficiency Testing

Each laboratory is required to verify the accuracy of their test methods. Participation in proficiency testing (PT) or another scientific means of assessing results is required to assess quality. For selected analytes (which are called regulated analytes), the laboratory must enroll in PT. Refer to Fast Facts 10: CLIA Regulated Analytes for the list of regulated analytes and CLIA Facts 28 for a list of approved PT providers. If the expansion of your test menu makes it necessary to enroll in PT for the first time, *LabGuide 8: Proficiency Testing* and CLIA Facts 26 through 30 have helpful information on enrolling in PT and the regulatory requirements affecting your enrollment.

For unregulated analytes the laboratory can either enroll in PT or perform Split Sample Analysis. For more information on setting up split sample analysis, refer to *LabGuide 9: Split Sample Analysis*. If the laboratory is utilizing Split Sample Analysis in place of PT for an unregulated analyte, the first series of specimens to be split should be performed right away, within 1 month of the addition.

Laboratories are expected to enroll in PT for the first available event following addition of a new regulated analyte. PT providers allow laboratories to add or delete analytes during the year, to accommodate changes in test menu. Be aware that a laboratory is not permitted to change PT providers mid-year. Once enrolled for a calendar year, the laboratory must remain with that provider for that year. You may enroll with an additional provider, if necessary to cover a test not offered by your current provider, but you may only switch currently enrolled testing to a new provider at the next enrollment period.

The PT requirements are different for testing added in

Current Complexity of Laboratory	To Add Moderate Complexity Testing	To Add High Complexity Testing
Waived/PPM	Verify all required positions are filled by personnel who meet moderate complexity requirements for education and experience. Verify that new specialty or subspecialty requirements are met. Note: Must change CLIA Certificate of Waiver or PPMP to Certificate of Accreditation.	Verify all required positions are filled by personnel who meet high complexity requirements for education and experience. Verify that new specialty or subspecialty requirements are met. Note: Must change CLIA Certificate of Waiver or PPMP to Certificate of Accreditation.
Moderate Complexity	Verify that any new specialty or subspecialty requirements are met.	Verify all required positions are filled by personnel who meet high complexity requirements for education and experience. Verify that any new specialty or subspecialty requirements are met.
High Complexity	Verify that any new specialty or subspecialty requirements are met.	Verify that any new specialty or subspecialty requirements are met.

Figure 2: Change of Complexity Scenarios for Personnel

Cytology. The performance of GYN Cytology (PAP smears) requires each individual engaged in the examination of gynecologic preparations to enroll and participate successfully in PT. The laboratory must assure that all staff examining gynecologic preparations are enrolled and have successful performance. For more details regarding the PT requirements for GYN Cytology, refer to criteria 778-781 in your Accreditation Manual.

Answer the questions in **Evaluation Grouping: Proficiency Testing** in the COLA Self-Assessment to verify you meet all the requirements for Proficiency Testing.

Verification of Performance Specifications

When adding an unmodified, non-waived, FDA-approved test to your menu, CLIA requires you to **verify** the manufacturer's stated performance specifications (in the package insert) for that test before you report patient results. The verification process confirms that the test performs as the manufacturer intended, taking into account the particulars of your laboratory environment, your personnel, and your patient population. For more information on this process, CLSI (formerly NCCLS) offers a number of documents that are helpful resources.

What Performance Specifications Need to Be Verified?

For unmodified, FDA-approved tests, you must verify **accuracy**, **precision**, **reportable range,** and **reference ranges**.

What if the Test is Not FDA-approved?

If you add a test to your menu that is not FDA-approved, or that was FDA-approved, but you have modified the procedure, then you must **establish** performance specifications. In addition to accuracy, precision, and reportable range, you must establish analytical sensitivity and specificity, normal values, and calibration and control procedures for these tests

Document all activities involved in verifying or establishing performance specifications. Retain this documentation for as long as the test method is in use and for 2 years after discontinuing the method.

Answer the questions in **Evaluation Grouping:**

Verification of Performance Specifications in the COLA Self-Assessment to verify you meet all the requirements for verification or establishment of performance specifications.

Calibration & Quality Control

After verifying the Performance Specifications for your new method, the next step is to define your laboratory's requirements for calibration and quality control. In the majority of test systems, the manufacturer has defined, based on the performance specifications and the reagent and test system stability, initial requirements for the number and type of samples to be used and the frequency of performance. The laboratory must determine if the manufacturer's requirements are supported by the results of its own study of performance specifications, and whether the requirements meet the minimum requirements of CLIA and COLA.

Figure 3 outlines the general requirements of CLIA/COLA for calibration and quality control. The laboratory must determine if it is subject to more stringent regulatory, manufacturer, or specialty-specific requirements. The laboratory must specify its exact requirements in its written policies and procedures.

Answer the questions in **Evaluation Grouping: Calibration** and **Evaluation Grouping: Quality Control** in the COLA Self-Assessment to verify you meet all the requirements for calibration and quality control.

Written Procedure

The laboratory must have a written procedure that provides step-by-step instructions for staff to perform each task associated with the test(s) being added. The laboratory may use manufacturers instructions (such as operator's manuals for equipment and package inserts for kits or reagents) to fulfill some of the requirements for a procedure. There are several required components that you will need to write yourself. These are items specific to your laboratory:

- Calibration and QC procedures, if different than manufacturer's requirements, or if manufacturer's requirements do not specify number, type, and frequency.
- Instructions for recording control results, evaluating results for acceptability, and instructions regarding whether to report results or retest specimens if controls are out of range. The manufacturer usually provides some guidance in the form of troubleshooting out of range controls, however COLA recommends that you define specific steps and the individuals to notify whenever out of range results are obtained in your laboratory.
- Reportable range and normal values as determined when verifying Performance Specifications.
- Defined alert (panic) values.
- Instructions for how to report results.
- Instructions for what to do if the test system is down.

Refer to *COLA LabGuide 1: Contents of a Procedure Manual* for additional assistance.

Compile the manufacturer's instructions with your written procedures. Prior to seeking the Laboratory Director's approval, ask a staff member to use the documents to perform a test. This allows you to verify that all steps are present, and to get feedback about anything

	Calibration	Quality Control
Number of Samples	• Follow manufacturer's requirements	• Two different levels (normal & abnormal or positive & negative) • Follow manufacturer's requirements if more stringent
Type of Sample	• Follow manufacturer's requirements	• Follow manufacturer's requirements • Same matrix as patients
Frequency	• At least every six months • Follow manufacturer's requirements if more stringent	• Each day of testing • As stated in specialty-specific requirements • Follow manufacturer's requirements if more stringent

Figure 3: General CLIA/COLA Requirements for Calibration and Quality Control

that might be confusing or unclear. This is a critical part of the process, as the written procedure will be the basis for training employees in how to perform the test.

Once you are satisfied with the written documents, provide them to the Laboratory Director to review, and approve. The director should sign and date the procedure with the date it is approved for use in the lab. Add these documents to your procedure manual and update the table of contents as necessary.

Answer the questions in **Evaluation Grouping: Organization** and **Evaluation Grouping: Procedure Manual** in the COLA Self-Assessment to verify you meet all the requirements for the procedure manual.

Personnel Training and Competency

Personnel must be trained to perform the new testing, and must demonstrate competency before testing patient samples that will be reported. If a new instrument is involved, the manufacturer will usually provide instrument training. Training for a new test must include:

- Patient preparation (if applicable), specimen handling, and specimen processing
- Reagent preparation, handling, and storage
- Maintenance, function checks (if applicable), and calibration
- Quality control and calibration procedures
- Test procedures and result interpretation
- Result reporting
- Troubleshooting

Competency can be assessed by:

- Direct observations of test performance
- Direct observation of performance of instrument maintenance and function checks
- Monitoring the recording and reporting of test results
- Reviewing worksheets, quality control records, calibration records, proficiency testing results, and preventive maintenance records
- Evaluating results obtained when testing previously analyzed specimens, internal blind testing samples, or previously tested proficiency testing samples
- Evaluating problem solving skills

If you involve testing personnel in the verification (or establishment) of performance specifications, you will already have some data regarding their ability to perform the test that can be used to assess competency.

Ensure competency is maintained by assessing competency every six months for the first year and annually thereafter, and conduct additional training when needed. Document all training and competency assessments.

Answer the questions in **Evaluation Grouping: Personnel** in the COLA Self Assessment to verify you meet all the requirements for personnel training and competency.

Specialty Specific Considerations

In addition to general requirements, both CLIA and COLA have specific requirements to address quality issues for critical aspects of testing in many of the specialties and subspecialties. Review the applicable evaluation grouping in the COLA Self-Assessment to verify you meet all the requirements for the new specialty.

REFERENCES

1. Final CLIA Regulations 2003, Part 493, Subparts I, K, and M
2. COLA Criteria for Quality Laboratory Performance, Accreditation Manual and Self Assessment Questions, Section III

Appendix 1
Specialties, Subspecialties, and Sample Tests

Specialty	Subspecialty	Sample Tests
Chemistry	Routine Chemistry	glucose, electrolytes, blood gas, basic chemistry panel
	Urinalysis	urine dipstick, urine sediment, urine pregnancy tests
	Endocrinology	thyroid tests (TSH, T4, T uptake), hormone tests (FSH, LH, Estradiol), serum pregnancy tests
	Toxicology	drug levels for therapeutic drugs (Theophyline, Digoxin) or detection of drugs of abuse (cocaine, barbiturates, amphetamines)
Hematology	Routine (includes Coagulation)	CBC, sed rates, reticulocyte counts, prothrombin time (PT), APTT, fibrinogen
Immunology	General	rheumatoid factor (RF), ANA, ASO, mono tests
	Syphilis Serology	RPR, darkfield exams
Immunohematology	ABO & Rh	blood typing
	Antibody Detection	antibody screens
	Antibody Identification	all antibody identification methods
	Compatibility	cross match
Microbiology	Bacteriology	rapid strep tests, gram stains, bacterial culture & identification (throat, urine, genital, blood, wound, etc.), susceptibility testing
	Mycobacteriology	AFB smear, AFB culture
	Mycology	KOH preps, dermatophyte culture, fungal culture, germ tubes
	Parasitology	pinworm prep, detection and/or identification of ova or parasites (O&P)
	Virology	influenza, RSV, rotavirus, viral cell culture
Pathology	Cytology	PAP smears, fine needle aspirations
	Histopathology, including:	frozen sections, tissue biopsy
	Dermatopathology	skin biopsy, MOHS surgery
	Oral Pathology	oral tissue biopsy

Appendix 2
Kay Responsibilites When Adding Tests

Laboratory Responsibility	COLA Responsibility
Identify tests to be added and research available test methods. Select method.	
Determine complexity and verify personnel qualifications. Hire new qualified individuals if necessary.	
Purchase necessary equipment, reagents, controls, and calibrators.	
Notify COLA within 60 days of addition.	Add to test menu, determine if this is a new specialty or subspecialty.
	Review laboratory compliance history and determine how compliance will be assessed.
Enroll in PT for next available event, or for unregulated analytes can elect to perform split sample analysis within 1 month.	Provide laboratory with Implementation Form to complete. Advise if onsite survey will be required.
Verify or establish performance specifications, calibration, and quality control requirements.	
Develop and obtain approval of written procedures.	
Conduct personnel training and initial competency assessment.	
Compile all documentation associated with implementation for Laboratory Director review and approval.	
Complete and submit Implementation Form to COLA for review after sign-off by Laboratory Director.	Verify acceptable completion and schedule onsite survey if required.
	Conduct onsite survey if necessary.
Make necessary revisions to requisition and reporting systems to accommodate new testing.	Notify laboratory and CMS of accreditation for new specialty or subspecialty.
Archive all data related to initial implementation. Data must be stored and maintained for 2 years beyond the date the test/method is discontinued.	
Begin patient testing.	

COLA
Lab Accreditation Through Education

Appendix 3: Implementation Form

COLA ID: _____ **CLIA ID:** _____

Laboratory Director: _____ **New Specialty/Subspecialty:** _____

Laboratory Name: _____ **New Test System:** _____

Laboratory Address: **Test Being Added:** _____

_____

_____

	Review the actions required under each heading. As each item is completed, enter the date and your initials in the adjacent columns.		
	Laboratory Responsibility	**Date Completed**	**Initials**
1	**Determine the complexity of new method. Check the appropriate box below.**		
	Waived: ❑ Moderate: ❑ High: ❑		
2	**Verify qualifications of current personnel** • Laboratory Director • Technical Consultant or Technical Supervisor • General Supervisor (if high complexity) • Testing Personnel		
	Current Staff: Qualified: ❑ Not Qualified: ❑		
	New staff recruited and hired. Submit COLA Personnel Forms for new staff.		
3	**Training & Competency**		
	Training sessions held.		
	Competency assessments performed.		
4	**Proficiency Testing or Split Specimen Analysis**		
	PT provider name and your account number:		
	First PT Event lab will perform:		
	For Unregulated Analytes: Complete 5 split specimens with acceptable results		
5	**Performance Specifications**		
	Precision & Accuracy		
	Reportable Range		
	Reference Range		

	Review the actions required under each heading. As each item is completed, enter the date and your initials in the adjacent columns.		
	Laboratory Responsibility	**Date Completed**	**Initials**
5	**Performance Specifications - continued**		
	Analytic Sensitivity & Specificity (only required if non-FDA-approved method or modification to FDA-approved method.		
6	**Calibration & Quality Control**		
	Calibration schedule established.		
	QC program established. • Frequency of QC: • Number of Controls:		
7	**Procedure Manual**		
	Draft written procedures and compile manufacturer's instructions.		
	Trial use of procedure to perform test.		
	Approval of procedure by laboratory director or designee.		
8	**Requisition & Reporting System**		
	Update requisition system to include new test(s).		
	Update reporting system to include new test(s).		
9	**Compliance Verification to COLA**		
	Complete applicable portions of COLA Self Assessment.		
	Submit completed form and all supporting documentation to laboratory director for review and appoval.		
	Laboratory director signature:		
	Submit copy of signed form to COLA and retain originals for your records.		