

# Laboratory Consultant Libby Knollmeyer: What is the Difference Between CLIA and COLA?

CLIA (**Clinical Laboratory Improvement Amendments of '88**) is the basic set of regulations governing all laboratories that test human specimens (with rare exceptions). It is the minimum standard for labs.

CLIA has given “deemed status” to several other agencies allowing them to accredit labs and inspect the labs in CLIA’s stead. **COLA** is one of these agencies (as are **CAP** and **The Joint Commission**). All accrediting agencies must be at least as strict as CLIA, or to phrase it a different way, all accrediting agencies must have the same regulations as CLIA does, and then may add additional regulations on top of the CLIA regulations if they wish.

There is little difference between CLIA and COLA from a **regulatory** viewpoint. COLA enforces a few more requirements than CLIA does, but the differences are relatively minor. One example is that COLA requires correlation studies be done when a new instrument is installed to compare the new instrument to an old instrument or a reference lab method and CLIA does not. Another is that CLIA requires an overlap of old control lot numbers to new control lot numbers but doesn’t specify a number of times they must be run together; COLA requires overlapping old and new 5 times. So there are differences, but it is pretty easy to see that the differences in regulations are not extreme. CLIA publishes their Interpretive Guidelines on the Internet for all to read so you have ready access to the information as to how a regulation is going to be applied; COLA does not and will not share their Interpretive Guidelines (they consider it proprietary information), so understanding

how a questionable regulation will be applied is left to a guess or a phone call to COLA headquarters in Maryland.

From a **personnel** standpoint, there is no difference between CLIA and COLA. COLA follows the CLIA requirements for personnel qualifications and responsibilities, both for moderately complex labs and for highly complex labs.

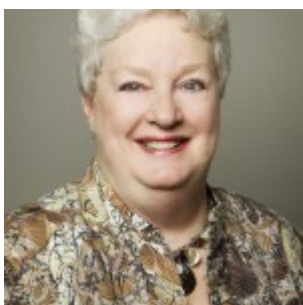
From an **inspection** standpoint, there can be notable differences, depending on the state in which the lab is located. CLIA is a federal program but is administered at the state level in each state. While the regulations they enforce are the same, the quality of the CLIA departments from one state to another varies widely. COLA is a nationwide program and the inspectors move freely between states as needed to inspect labs. Both agencies train their inspectors, so in a perfect world all inspections would be the same within an agency. Unfortunately, however, that is not the real life situation. The quality of the inspectors and the inspections they perform can vary widely "" in each agency. In many states, CLIA is short-staffed so delays are common. On the whole, COLA is probably a little more uniform throughout the country than CLIA is, but CLIA is usually more dependable with post-inspection routine and follow-up than COLA.

The **costs** associated with CLIA and COLA are pretty much the same. Both base their costs on the number of non-waived tests performed in a year's time. All labs pay CLIA a Certificate Fee""the cost of renewing the CLIA identification number. And all non-waived labs pay a Compliance Fee to cover the cost of their inspection, but the Compliance Fee is billed by the inspecting agency, so if you're inspected by CLIA the Compliance Fee will be billed by CLIA and if you are accredited by COLA, the COLA fee covers the cost of the inspection.

Several states have state lab regulations on top of CLIA regulations that are enforced. Pennsylvania, New York,

Massachusetts, Maryland, Illinois, and California are several examples. Whenever there is state licensure of labs in addition to CLIA licensure, the fees will usually be higher because there will be both a CLIA and a state fee. If your lab is located in a state with additional state regulations, be sure and find out how the state regulations differ from CLIA and/or COLA (depending on which you choose for compliance). And be aware that when CLIA amends a regulation to make it less strict, COLA and/or the state may not follow suit. Also be aware that if your lab fails to maintain accreditation with one of the agencies other than CLIA, they will lose their CLIA Certificate as well unless they can pass a CLIA inspection. The accrediting agencies carry just as much weight as does CLIA.

Whenever I am asked which agency I recommend for a new lab, my answer is "it depends"! In some states, CLIA is absolutely the best choice (North Carolina is one of those states) because the department is very well run and the inspectors are very well trained and highly accessible when assistance is needed. In other states, CLIA is a disaster and COLA is absolutely the best choice (California and Louisiana being two examples). In the great majority of states, it really doesn't matter which agency is chosen because overall they both do excellent jobs.



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