

CLIA FREQUENTLY ASKED QUESTIONS

What is CLIA '88?

CLIA '88 stands for Clinical Laboratory Improvement Amendments of 1988. It is a series of federal laws that were enacted to regulate laboratory testing, ensuring high quality, safe, reliable and accurate testing in laboratories throughout the United States. It established new standards for laboratory personnel, quality control and quality assurance. It is based on the complexity and risks of the test performed. Tests are classified into one of three categories based on their complexity: waived, moderate complexity, and high complexity.

Why do I need a Certificate of Waiver?

If you are a user of a waived test, meaning if you are a laboratory, physician office, pharmacy, or other entity performing testing of materials derived from the human body for the purpose of diagnosis, prevention treatment or health assessment, then you are required to register with CMS, formerly HCFA. To do so you must obtain a CLIA Certificate of Waiver. The fee for the Certificate of Waiver is \$150 and is valid for two years.

How to I get a CLIA Certificate of Waiver?

- Download the file "CLIA Application," found on the Unicity Start Up Kit web page and print it out.
- Fill out the application and mail it back to your state department of health. Do not send a check with your application.
- The state department of health will put the information into the CMS computer and this will generate a coupon for the fee, which is \$150 for 2 years. The coupon will have your CLIA ID number on it.
- You may start testing when you receive the coupon with your CLIA ID number on it.

In addition to obtaining a Certificate of Waiver, what else do I need to do before I begin testing?

Contact your state agency for additional requirements in your state. For the list of state agencies, download the document "CLIA State Regulatory Entities" found on the Unicity Start Up Kit web page.