What is a CLIA certificate of waiver?
The CLIA certificate of waiver is a registration with the U.S. Department of Health and Human Services that allows physicians or medical office personnel to collect a sample and perform a laboratory test within their office. In the U.S., the Centers for Medicare and Medicaid Services (CMS) regulates all examination of human specimens (e.g., tissue, blood, urine, etc.) for diagnosis, prevention, or treatment purposes through the Clinical Laboratory Improvement Amendments (CLIA). The objective of the CLIA program is to ensure quality laboratory testing, even at the point-of-care.

Why do we need a CLIA certificate of waiver if the test is CLIA-waived?
There are three different levels of complexity: waived, moderate, and complex. The complexity level determines what is required to administer a particular test. For instance, waived tests (like AdenoPlus™) have the lowest level of complexity and can be easily performed by most medical office personnel with minimal training. Such tests have been determined by the FDA to be so simple that there is little risk for error. However, tests that receive the moderate and higher complexity designations may require costly additional equipment, technical certification, and even regulatory oversight.

Note: CLIA-waived tests require medical facilities to have a CLIA certificate of waiver in order to administer and receive reimbursement for using the test.

What is the process to obtain a CLIA certificate of waiver and are there costs associated with this?
Every state has its own requirements and fees regarding CLIA certification. However, most states only require the standard federal CLIA application (CMS-116) to be completed. This 4-page application can be found on: RPSdetectors.com. After completion, submit the form to your state health department. Upon processing the application, your facility will be billed a certification fee of $150.00, renewable every two years. Some states may require additional forms, have additional fees, or have other specific requirements regarding CLIA certification. Contact RPS for more information about your state's CLIA requirements.

How long will it take to receive our CLIA certificate of waiver?
Depending on your state health department, it can take between 4-12 weeks to receive your CLIA certificate. The CLIA certificate of waiver is necessary for state and federal compliance, and provides the benefit of facilitating provider reimbursement for the use of CLIA-waived tests.

Does RPS provide assistance with the CLIA application process?
Yes! RPS provides assistance to customers filling out the CLIA application. Our experienced staff provides step-by-step instructions via phone or email to expedite the application process. For more information, contact an RPS inside sales representative toll-free at 877-921-0080.