

Dear Laboratory Director:

Your laboratory has been selected to be surveyed as part of the Clinical Laboratory Improvement Amendment (CLIA) program's efforts to visit and gather information about the testing being performed in Certificate of Waiver (COW) laboratories in the United States. Your survey will take place on (enter date and time).

The CLIA program, through the State Departments of Health, will conduct on-site surveys of laboratories holding COW certificates to evaluate their testing practices and to provide technical assistance to those laboratories where test quality concerns are found. Our authority to survey your laboratory can be found in 42 CFR 493.1775(b) of the CLIA regulations. These surveys will include a wide range of laboratories and will represent an opportunity for the CLIA program staff and the laboratories to share their knowledge and experiences.

The surveys will be conducted in a manner similar to the current CLIA compliance surveys; i.e., evaluating the ability of the laboratory to ensure quality test results, but your laboratory will not be charged for the survey. A State surveyor will contact your laboratory by telephone to confirm the date and the time of this appointment approximately 10 days prior to the projected survey date. The on-site time in your laboratory is expected to be approximately one or two hours. A discussion about the survey findings and information about how to correct any problems affecting test results, will be provided at the conclusion of the survey. If the State identifies any concerns, you will subsequently receive a written report containing the findings, recommendations for correction and a contact person at the State, should you require more information. It is our intent that the focus of these inspections be educational only; however, if any serious risk to human health remains uncorrected, we may have to pursue further action. We will also re-visit a small number of the laboratories that have problems to ensure they are providing good quality testing.

If you have any questions about this survey and/or the CLIA program, please view the CLIA web site at: <http://www.cms.hhs.gov/clia>