Dear Laboratory Director:

Representatives of the _(State Agency)_surveyed your laboratory on_(Date)_ for CLIA purposes. Requirements contained in the former regulations, published in 1992, were met; however, the surveyor(s) identified requirements contained in the final regulations published on January 24, 2003 that were effective on April 24, 2003, that were not met.

Findings and Observations Under Revised CLIA Rules

During the exit interview, the __(State Agency)__representative discussed items regarding provisions contained in the 2003 revisions of the CLIA regulations. At the present, CMS is responding to such findings by educating laboratory directors about the Quality Control (QC) regulatory requirements that may be relatively new to laboratories. We are listing these items in a letter, rather than the formal survey report as part of this educational effort. CMS expects that this process will allow laboratories to become more knowledgeable about these recent requirements in order to make informed compliance decisions.

Additionally, since the publication of the 2003 final regulations and accompanying guidelines, CMS has identified innovations in technology and received input from technical experts that may lead to further modifications of QC policies in our interpretative guidelines. CMS is also undertaking a number of processes to acquire additional information, data and scientific input relative to such QC and technological advances in order that our policies will reflect these innovations.

Therefore, so long as laboratory directors, at a minimum, review manufacturers' QC instructions, find those instructions to reasonably monitor the accuracy of the analytic process and the laboratory then follows those manufacturers' instructions, we plan to continue the educational process noted above until any merited changes are incorporated into our guidelines, for the QC requirements contained in the 2003 modifications of the CLIA regulations.

At the time of your survey on _(date)__ your lab was not in compliance with the following provisions contained in the revised CLIA regulations:

********** You will need to customize this portion according to the compliance problems identified in each lab**********

********** Please include the remainder of the letter in your correspondence**********

Additional information concerning these items may be found on the CLIA website at www.cms.hhs.gov/clia. There are CLIA regulations, Interpretive Guidelines and several brochures on the web site, that are helpful in understanding the revised regulations.

The _(State Agency)_ representative will be contacting you to determine if your laboratory has any questions regarding the areas identified during the survey. In the meantime, if you would like additional information or need further assistance, please contact _(name and phone number)_____.

Sincerely,

CLIA Inspector
DHSS Office of Health Facilities
Licensing and Certification