Department of Health & Human Services
Centers for Medicare & Medicaid Services
61 Forsyth St., Suite. 4T20
Atlanta, Georgia 30303-8909

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

October 26, 2010

David K. Turgeon PHD, D-ABMM, Director
Centers for Disease Control and Prevention
1600 Clifton Road NE.
Atlanta, GA 30333

CLIA# 11D0668319

Dear Dr. Turgeon:

A Federal Direct Survey was conducted at the Centers for Disease Control and Prevention laboratory by Region IV federal surveyors on September 13-22, 2010. Based on this survey, we found that your laboratory is in compliance with the Condition-level requirements of Clinical Laboratory Improvement Amendments of 1988 (CLIA) Conditions.

However, we did provide some recommendations, and we are enclosing a complete listing, of those recommendations.

1. All of your laboratories have a Quality Assurance (QA) plan of some form. However, some of the QA plans are more industrial oriented rather than CLIA oriented. The laboratories should concentrate on CLIA QA to come into CLIA compliance.

2. In one laboratory, CLIA testing had been transferred from another laboratory. The first laboratory had not performed PT for a particular test. This could have resulted in a Condition level deficiency for the first laboratory. However a Condition was not cited because corrections were made by the second laboratory on-site.

3. Customer satisfaction form for Laboratory testing was discussed at the exit conference. It is only a recommendation; however the questionnaire would benefit the laboratories and serve as a very good Quality Assurance tool.

4. Laboratories should verify that personnel competency reviews follow, as applicable, the specific instructions at 493.1451(b) (8)

We appreciate your efforts and steps taken to ensure compliance with the CLIA regulations, and thank you for your cooperation.

If you have any questions, or would like additional information, please contact Martha Kay Personette at 404-562-7455 or Regina Holmes at 404-562-7450 of the CMS Regional Office.