**EXHIBIT 246**

**MODEL LETTER FROM THE REGIONAL OFFICE NOTIFYING A STATE-OPERATED LABORATORY OF CITED DEFICIENCIES AND REQUESTING A PLAN OF CORRECTION**

(**Date**)
Director Name
Name of State-Operated Laboratory
Address
City, State, ZIP Code

Dear (**Laboratory Director**):

RE: CLIA Number (**CLIA Number**)

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Public Law 100-578), and bill for services provided to Medicare beneficiaries or Medicaid recipients under Titles XVIII and XIX of the Social Security Act, it must comply with all CLIA requirements (42 CFR, Part 493).

The (**name of Regional Office**) conducted a certification survey of your laboratory on (**date**). The attached Statement of Deficiencies and Plan of Correction (Form CMS 2567) identifies the noncompliance with CLIA requirements which was found during that survey. Specifically, the following CLIA Condition(s) (**was, were**) not met: (**cite the Conditions which are out of compliance**). Additionally, your laboratory is out of compliance with the following standard level requirements: (l**ist them**).

Facilities that do not meet a CLIA Condition may not be certified for participation in the CLIA program. You must take immediate steps to correct the condition-level noncompliance.

We request that you indicate your plan of correction on the right side of the form, matching your responses with each deficiency on the left. Please indicate your anticipated completion dates in the appropriate spaces. The plan of correction should be signed and dated by you and returned to our offices no later than (**10 days from the date of this letter**).

In addition to the plan of correction, if you provide this office with a credible allegation of compliance, we will conduct a follow-up visit within approximately 30-45 days from the date of the original survey. A credible allegation of compliance is a written statement or written documentation that is:

- Is presented by a representative of a laboratory which has a history of a commitment to compliance and taking corrective action when required;

- Realistic in terms of the possibility of the corrective action being accomplished between the date of the survey and the date of the allegation of compliance; and

- Indicates correction of the noncompliance.

If you are found to still be out of compliance with any CLIA Condition at the time of the follow-up visit, we may impose sanctions.

If you have any questions, please call (**State representative in RO**).

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Enclosure

cc: State Agency or other