

**EXHIBIT 112**

**CLIA REQUIREMENTS NOT MET - LABORATORY  
OUT OF COMPLIANCE**

**(Date)**

Name of Laboratory Director

Name of Facility

Street Address

City, State, ZIP Code

CLIA Number\_\_\_\_\_:

Dear **(Laboratory Director Name)**:

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 493). The date of survey and date(s) of revisit(s) reports of your laboratory have been reviewed by this office and transmitted to the Division of Health Standards and Quality Regional Office.

The survey reports reveal there are areas of deficiencies that are preventing your laboratory from being in compliance with the CLIA Requirements. Based on our review, the following Conditions are not in compliance:

**(List all Condition level regulatory citations)**

The Plan of Correction you have submitted has been reviewed and forwarded to the Regional Office. Since your facility does not comply with all requirements, we are recommending a certification of non-compliance to the Regional Office and that the following sanction(s) be imposed and/or enforcement action(s) be taken:

**(List alternative and/or principal sanctions to be imposed and/or enforcement action(s) to be taken)**

The Regional Office has final authority for this determination and will inform you of its determination and the appeals procedures.

(Name)

Page 2

(Date)

If you have any questions regarding this matter, please contact (**phone number and contact name**)

Sincerely yours,

Enclosures