

EXHIBIT 113

CLIA REQUIREMENTS NOT MET - IMMEDIATE JEOPARDY

(Date)

Laboratory Director Name
Name of Facility
Street Address
City, State, ZIP Code

CLIA Number _____:

Dear **(Laboratory Director Name)**:

Our records indicate that **(name of laboratory)** is certified to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578.

Federal regulations require surveys to determine whether or not a laboratory is in compliance with the applicable regulations. Compliance with such regulations is a condition of certification for the federal program.

The **(name of State survey agency)** conducted a survey on **(the last date of survey)** and issued a Statements of Deficiencies and Plan of Correction (Form CMS-2567). At that time it was determined that the following deficiencies exist, which pose immediate jeopardy to the patients served by your laboratory:

(List all Condition level regulatory citations)

Because of the seriousness of these deficiencies, your laboratory no longer meets the requirements to perform testing under CLIA. As a result, this office has contacted the Centers for Medicare & Medicaid Services' (CMS) Regional Office (RO), and has recommend a certification of noncompliance and the following sanction(s) be imposed and/or enforcement action(s) be taken:

(List sanctions to be imposed including rationale, projected effective date, duration of the proposed sanction(s) and/or enforcement actions(s) to be taken)

Please be advised that sanctions and/or enforcement action can be rescinded only when compliance with the above deficiencies is verified. If you believe that correction has been accomplished, it is your responsibility to contact the RO with a credible allegation of compliance, so that the removal of the jeopardy can be verified.

(Name)

Page 2

(Date)

The RO will advise you of the sanctions(s) to be imposed and/or enforcement action which will be taken if the jeopardy is not removed. At that time you will also be notified of your appeal rights.

If you have any questions, or would like additional information, please contact **(State agency contact person)** at **(phone number)** or the CMS-RO directly.

Sincerely yours,

State Agency Representative

Enclosures