

EXHIBIT 248

**NOTICE OF PROPOSED LIMITATION, SUSPENSION, OR REVOCATION OF
THE CLIA CERTIFICATE; OPPORTUNITY FOR A HEARING:**

NO IMMEDIATE JEOPARDY

CERTIFIED MAIL -- RETURN RECEIPT REQUESTED

(Date)

CLIA Director Name

Name of Laboratory

Address

City, State, ZIP Code

Dear **(Laboratory Director)**:

RE: Notice of Proposed Limitation, Suspension, or Revocation of the CLIA Certificate;
Opportunity for a Hearing
CLIA Number **(CLIA Number)**

Clinical Laboratory Improvement Amendments of 1988: 42 U.S.C. 263a

Notice is hereby given that we propose to (fill in suspend, limit, or revoke) your Clinical Laboratory Improvement Amendments of 1988 (CLIA) certificate, which was issued to your laboratory on (fill in date) under the authority of the (CLIA) (Section 353 of the Public Health Service Act, 42 U.S.C. 263a) and the provisions of Title 42 of CFR, Part 493. This action will be effective (date).

(In the case of a limitation of the CLIA certificate, insert the following:)

Due to the noncompliance with the CLIA Conditions specified in the enclosure, under a limitation of your CLIA certificate, you would be prohibited to test in the following specialties and/or subspecialties: **(list them)**.

You will be issued a revised certificate.

If you disagree with this determination, you may request an administrative hearing within 60 days of your receipt of this notice. The request must be in writing by you or your legal representative, and must contain the following information:

(Name)

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(Date)

1. The specific issues or findings with which you disagree; and
2. The specific basis for contending that the State agency's or the CMS' findings are incorrect.

Administrative hearings are conducted by the Departmental Appeals Board of the Department of Health and Human Services (DHHS). If you request a hearing, the **(limitation, suspension, or revocation)** of your CLIA certificate will not be effective until after the hearing decision is rendered. If you do not request a hearing, the **(limitation, suspension, or revocation)** of your CLIA certificate will become effective **(date)**, unless you correct the noncompliance. If we determine that any of your deficiencies has become more serious so as to be considered to pose immediate jeopardy to the health and safety of individuals served by the laboratory or that of the general public, we may suspend or limit your CLIA certificate prior to the hearing.

If additional expenses are incurred to conduct future visits to verify correction of deficiencies, to impose sanctions, and/or for surveyor preparation for an attendance at an Administrative Law Judge hearing, DHHS assesses an additional fee to include these costs. The additional fee is based on the actual resources and time necessary to perform these activities.

In the interim we will be imposing the following alternative sanction **(list them)**. If a hearing is requested, your CLIA certificate will remain in effect, and may need to be reissued if it is due to expire, until a hearing decision is effective.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Enclosure

cc: State Agency