

EXHIBIT 235

**NOTICE OF SUSPENSION OR LIMITATION
OF THE CLIA CERTIFICATE: IMMEDIATE JEOPARDY**

OVERNIGHT MAIL

(Date)

CLIA Director Name

CLIA Name

Address

City, State, ZIP Code

Dear **(CLIA Director Name)**:

Re: CLIA Number **(CLIA Number)**

Suspension or Limitation of the CLIA Certificate

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

This is to inform you that the Clinical Laboratory Improvement Amendments of 1988 certificate for your laboratory will be **(suspended, limited)** due to noncompliance which we have determined constitutes immediate jeopardy to the health and safety of patients served by your laboratory, based on the survey conducted by **(State Agency)** on **(date)** and the information provided to us on the Statement of Deficiencies and Plan of Correction (Form CMS-2567). This action is taken under the authority of CLIA, §353 of the Public Health Service Act (PHSA), 42 U.S.C. 263a and the provisions of 42 CFR, Part 493, Subpart R.

(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 will be prohibited to test in the following specialties and/or subspecialties:

(List specialties/subspecialties, along with the rationale for the determination of immediate jeopardy). You will be issued a revised certificate.

(In the case of a suspension of the CLIA certificate, also list the Conditions which are out of compliance, and the rationale for the determination of immediate jeopardy.)

In accordance with §353 of the PHSA, the **(suspension, limitation)** will be imposed on **(date of at least 5 days following the receipt of this letter, which should be sent via overnight mail)**, and will continue to be imposed until you remove the immediate

(Name)

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(Date)

jeopardy, or an administrative hearing decision is rendered if you appeal the determination. The revisit which was conducted by the **(State survey agency's name)** on **(date)** showed that an immediate jeopardy situation still exists in your laboratory.

Additionally, the alternative sanctions of **(list them, if you determine to impose them)** will be imposed on **(date of at least 5 days following the receipt of this letter)**.

Approval to receive payment from Medicare and Medicaid for services rendered will be cancelled on **(same date as other sanctions - 5 days following the date of receipt of this letter)**.

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:

1. The specific issues or findings with which you disagree; and
2. The specific basis for contending that the State agency's or the Centers for Medicare & Medicaid Services' findings are incorrect. Additional evidence may also be presented at the hearing, and you may be represented by counsel.

Administrative hearings will be conducted by the Departmental Appeals Board of the Department of Health and Human Services (DHHS). 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.

Please notify us immediately if you believe that the immediate jeopardy has been removed.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Enclosure

cc: State Agency