EXHIBIT 237

MODEL LETTER ANNOUNCING TO AN ACCREDITED LABORATORY AFTER A SAMPLE VALIDATION SURVEY OR A SUBSTANTIAL ALLEGATION OF NONCOMPLIANCE SURVEY THAT IT DOES NOT COMPLY WITH ALL CLIA CONDITIONS AND THAT THERE EXISTS IMMEDIATE JEOPARDY TO THE HEALTH AND SAFETY OF INDIVIDUALS OR THAT OF THE GENERAL PUBLIC

(**Date**)

Director Name
CLIA Name
Address
City, State, ZIP Code

Dear (**Director Name**):

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

Section 353(e) of the Public Health Service Act (PHSA) and implementing regulations provide that a laboratory accredited by an approved accreditation organization will be deemed to meet the conditions of the Clinical Laboratory Improvement Amendments of 1988 (CLIA). 42 CFR Part 493, Subpart E, requires the Centers for Medicare & Medicaid Services (CMS) or its agent to conduct a survey of an accredited laboratory on a representative sample basis or in response to a substantial allegation of noncompliance. If, in the course of such a survey, a laboratory is found to have deficiencies with respect to compliance with applicable CLIA Conditions, CMS will monitor the correction of any deficiencies until such time compliance is achieved or the certificate of accreditation is revoked. Laboratories accredited by (name of accreditation organization) are deemed to meet CLIA Conditions.

A survey was conducted at (**name of laboratory**) by the (**State survey agency**) on (**date**). At the conclusion of this survey, the findings were discussed with (**you or director's name**) and (**you, he, she**) was informed that conditions within (**name of laboratory**) posed an immediate jeopardy situation. Specifically, the laboratory does not meet the following CLIA condition(s):

(**Cite conditions**).

(Attach Form CMS -2567 and/or explanation of the immediate jeopardy findings.)

When a laboratory, regardless of its accreditation status, is found to be out of compliance with one or more CLIA Conditions, and immediate jeopardy exists, the laboratory is at risk of losing its certificate of accreditation. Such a determination has been made in the case of (**name of laboratory**) and, accordingly, this laboratory will be subject to:

(**Cite sanctions imposed/proposed**).

If the immediate jeopardy is not removed by (**no more than 23 days from the last day of the survey**) we will (**suspend, limit**) your CLIA certificate on (**date**) (**and suspend all or part of your Medicare payment - if applicable**). If you provide this office with a credible allegation of compliance, the (**State agency**) will conduct a follow-up visit as soon (**or date**) as possible. A credible allegation of compliance is a statement or documentation:

- Made by a representative of a laboratory with a history of having maintained a commitment to compliance and taking corrective action when required;
- That is realistic in terms of the possibility of the corrective action being accomplished between the date of the survey and the date of the allegation; and
- That indicates the removal of the immediate jeopardy or the resolution of the deficiencies.

If the immediate jeopardy is removed, but one or more Conditions remain out of compliance, we will not suspend or limit your certificate. You will be given additional time to come into compliance. However, we may impose one or more of the following alternative sanctions until compliance is reached:

- Directed plan of correction and directed portion of a plan of correction;
- Suspension of all or part of Medicare payments (if laboratory participates in the Medicare program);
- State onsite monitoring; and/or
- Civil money penalty.

In accordance with §353(i)(2) of the PHSA, the (**suspension or limitation**) may be imposed prior to an administrative hearing, and will continue to be imposed until you remove the immediate jeopardy, or an administrative hearing decision is rendered. In accordance with 42 CFR 493.1844, 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 to this office, and must contain the following information:

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

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.

If you have any questions, or would like additional information, please contact (**State agency representative**) at (**phone number**) or the CMS Regional Office at (**phone number**).

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

cc:
Accreditation Organization
State Agency or other
CMS Agent (if applicable)