EXHIBIT 238

MODEL LETTER ANNOUNCING TO AN ACCREDITED LABORATORY AFTER A SAMPLE VALIDATION SURVEY THAT THE LABORATORY DOES NOT COMPLY WITH ALL THE CLIA CONDITIONS:

NO IMMEDIATE JEOPARDY

(**Date**)
CLIA Director Name
Name of Laboratory
Address
City, State, ZIP Code

Dear (**Laboratory Director**):

RE: CLIA Number (**CLIA Number**)

Section 353(e) of the Public Health Service Act, and implementing regulations, provide that a laboratory accredited by an approved accreditation organization will be deemed to meet all conditions of the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

42 CFR Part 493, Subpart E, authorizes the Centers for Medicare & Medicaid Services (CMS) to conduct, on a representative sample basis or in response to substantial allegations of noncompliance, surveys of accredited laboratories as a means of validating the performance of an accreditation organization. If, in the course of such a survey, a laboratory is found to have deficiencies with respect to compliance with CLIA requirements, we are required to keep the laboratory under State survey agency review, until its CLIA deficiencies have been corrected, and it is in compliance with all applicable CLIA conditions.

A sample validation survey was conducted at (**name of laboratory**) by the (**State survey agency**) on (**date**). Based on this survey we find that your laboratory is not in compliance with all applicable CLIA Conditions. A complete listing of all deficiencies found by the (**State survey agency**) was previously furnished to your laboratory, and another copy is enclosed with this letter. These deficiencies have been found to be of such a serious nature as to substantially limit your laboratory's capacity to render adequate services, and prevent it from being in compliance with the CLIA Conditions. Specifically, your laboratory does not meet the following CLIA Condition(s):

(**Cite Conditions**).

If you have not already done so, you are requested to submit to the (**State survey agency**) a plan of correction no later than 10 days from the date you receive this letter. In addition to the plan of correction, if you provide this office with a credible allegation of compliance, we will conduct a follow-up visit as soon as possible. A credible allegation of compliance is a statement or documentation that:

- Is made by a representative of a laboratory with a history of having maintained a commitment to compliance and taking corrective action when required;
- 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
- Indicates the resolution of the deficiencies.

Facilities that do not meet one or more CLIA Conditions may not be certified for participation in the CLIA program. You must take steps to bring any unmet conditions into compliance immediately.

In accordance with the enforcement provisions specified in 42 CFR Part 493, Subpart R of the regulations, failure to comply with the CLIA conditions may result in CMS imposing one or more of the following alternative sanctions until compliance has been 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 on-site monitoring; and/or
- Civil money penalty.

If you are found to be out of compliance with any CLIA condition at the time of the follow-up survey, CMS may also take the following principal sanctions against your CLIA certificate:

- Limitation of the CLIA certificate;
- Suspension of the CLIA certificate; or

- Revocation of the CLIA certificate; and

- Cancellation of the laboratory's approval to receive Medicare payment for its services (if laboratory participates in the Medicare program).

When your deficiencies have been corrected and it has been found that all applicable CLIA Conditions are met, your laboratory will not be subject to further sanctions or State agency follow-up surveys.

Within 10 days after the receipt of this notice, you may submit to (**State survey agency**) or to CMS written evidence or any other information relating to the deficiencies found. In accordance with 42 CFR 493.1844, you may also 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:

1. The specific issues or findings with which you disagree; and

2. 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 request an administrative hearing, alternative sanctions may be imposed prior to the hearing or until CMS determines that the noncompliance on which the sanctions are based has been corrected.

Copies of this letter are being forwarded to the (**State survey agency**) and to the (**accreditation organization**).

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

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