

**EXHIBIT 227**

**MODEL LETTER ANNOUNCING TO THE CLIA-EXEMPT LABORATORY  
AFTER A SAMPLE VALIDATION OR SUBSTANTIAL ALLEGATION  
OF NONCOMPLIANCE SURVEY, THAT IT DOES NOT COMPLY  
WITH APPLICABLE PROGRAM REQUIREMENTS**

**(Date)**

Director Name  
CLIA-Exempt Laboratory Name  
Address  
City, State, ZIP Code

Dear **(Director Name)**:

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

Section 353(p) of the Public Health Service Act, permits the Secretary to exempt a laboratory in a State that has demonstrated that its laboratory licensure laws are equal to or more stringent than the Clinical Laboratory Improvement Amendments of 1988 (CLIA) requirements. Based on this authority, the Centers for Medicare & Medicaid Services conducts sample validation surveys to ensure that CLIA requirements continue to be met by approved State licensure programs and the laboratories they license (CLIA-exempt laboratories). If, in the course of such a survey, a CLIA-exempt laboratory is found to have deficiencies with respect to compliance with CLIA requirements, the State in which you are licensed is required to take the appropriate enforcement action and monitor the correction of deficiencies.

A **(sample or complaint)** validation survey was conducted at **(name of laboratory)** on **(date)**. At the conclusion of this survey, the findings were discussed with **(director's or designee's name)** and **(he, she)** was informed that conditions within **(name of laboratory)** pose an immediate jeopardy **(indicate whether or not deficiencies cited constitute immediate jeopardy)**. Specifically, the laboratory does not comply with the following CLIA Condition(s) and/or standard(s):

**(Cite conditions and/or standards).**

We have enclosed a complete listing of all deficiencies (Form CMS-2567, Statement of Deficiencies and Plan of Correction) found by CMS surveyors.

When a laboratory, regardless of its CLIA-exempt status, is found to be out of compliance with one or more comparable CLIA Conditions based on a (sample or complaint) survey and immediate jeopardy has been determined to exist, the laboratory must take prompt action to remove the jeopardy.

(Name)

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(Date)

We have informed the State of the survey findings and have recommended that the State take enforcement action if the cited deficiencies are not corrected by **(date)**.

The results of this survey may be made available to the public in accordance with the Federal Freedom of Information Act disclosure provisions.

Sincerely yours,

Associate Regional Administrator  
(or its equivalent)

Enclosure(s)

cc:

Central Office

CMS Agent (if applicable)