

EXHIBIT 231

**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
(NO IMMEDIATE JEOPARDY)**

(Date)

Director Name
Name of Laboratory
Address
City, State, ZIP Code

Dear **(Director Name)**:

Re: **(Name of CLIA-Exempt Laboratory)**
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 Clinical Laboratory Improvement Amendments of 1988 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 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 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.

We have informed the State of the survey findings, and it will be responsible for monitoring the correction of your deficiencies. We have directed the State to take enforcement action if the cited deficiencies are not corrected within an acceptable period of time. The State will report any enforcement action taken to us.

(Name)

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(Date)

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

A copy of this letter has been forwarded to the **(name of State laboratory program)**.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Enclosure(s)

cc: Central Office CMS Agent (if applicable)