

**EXHIBIT 230**

**MODEL LETTER ANNOUNCING TO THE STATE LABORATORY  
LICENSURE PROGRAM THAT CMS WILL SEEK  
A TEMPORARY INJUNCTION OR RESTRAINING ORDER  
TO ENJOIN CONTINUED OPERATION**

**(Date)**

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

Dear \_\_\_\_\_:

Re: **(Name of CLIA-Exempt Laboratory)**  
**CLIA Number (CLIA Number)**

Section 353(j) of the Public Health Service Act and implementing regulations specifies that if the Secretary has reason to believe that the continuation of any activity by a laboratory would constitute a significant hazard to the public health, the Secretary may bring suit in U.S. District Court to enjoin continuation of the specific activity or, if necessary, to enjoin the continued operation of the laboratory.

A survey was conducted at **(name of laboratory)** on **(date)**. At the conclusion of this survey the findings were discussed with the **(director's name)** and **(you, he, she)** was informed that the Conditions within **(name of laboratory)** pose a significant hazard to the public health. Specifically, the laboratory does not meet the following Clinical Laboratory Improvement Amendments of 1988 (CLIA) Condition(s) and/or standards:

**(Cite condition(s) and/or standard(s)).**

We have already informed the **(name of laboratory)** on **(date)** of these deficiencies. However, because you failed to take the appropriate enforcement action against the **(name of laboratory)**, we will file suit in the U.S. District Court **(for the district in which the laboratory is located)** to enjoin the continued operation of the **(name of laboratory)**. Additionally, your refusal to take the necessary enforcement action, may jeopardize the approval and/or renewal of your licensure program.

This action can only be averted by correction of the deficiencies that cause the significant hazard to the public health or by the imposition of an appropriate enforcement action by your office.

**(Name)**  
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**(Date)**

Sincerely yours,

Associate Regional Administrator  
(or its equivalent)

Enclosure(s) cc: Central Office