EXHIBIT 228

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

(**Date**)

State Laboratory Program Name
Address
City, State, ZIP Code

Dear _____:

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 (CLIA) requirements. Based on this authority, the Centers for Medicare & Medicaid Services (CMS) conducts sample and complaint validation surveys to ensure that CLIA requirements continue to be met by approved State licensure programs and the laboratories they license. If, in the course of such a survey, a CLIA-exempt laboratory is found to have deficiencies with respect to compliance with CLIA requirements, you are required to take the appropriate enforcement action and monitor the correction of deficiencies.

A (**sample or complaint**) survey was conducted at the (**name of laboratory**) on (**date**). CMS found Conditions within the laboratory that pose an immediate jeopardy to the general public. We have enclosed a listing (Form CMS-2567, Statement of Deficiencies and Plan of Correction) of all deficiencies found by the CMS surveyors during the survey.

We have informed the (**name of laboratory**) of our survey findings and that you will contact the laboratory regarding correction of the deficiencies and enforcement action.

We will contact you within 15 days from the date of this notice to verify that you have taken appropriate enforcement action. Unless an appropriate enforcement action is taken or the deficiencies have been corrected we may bring suit in the U.S. District Court to enjoin continuation of the activity that is causing the hazard or enjoin the continued operation of the laboratory in accordance with 42 CFR 493.1846.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Enclosure(s)

cc: Central Office