

EXHIBIT 1B-2

MODEL LETTER TRANSMITTING CLIA APPLICATION AND FORM CMS-1513 TO LABORATORIES

(Date)

Laboratory Director
Laboratory Name
Address
City, State, ZIP Code

Dear (Laboratory Director Name):

On February 28, 1992, the Department of Health and Human Services published regulations in the Federal Register implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA). CLIA requires every facility that tests human specimens for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of a human being to meet certain Federal requirements. In addition, the CLIA legislation requires financing of all regulatory costs through fees assessed to laboratories. CLIA applies to any facility performing laboratory testing as outlined above, even if only **one** or a few basic tests are performed, and even if you are not charging for testing.

Prior to performing and reporting test results, you must register with the CLIA program. The enclosed CLIA application (Form CMS-116) collects information about your laboratory's operation. This information is necessary to assess fees, to establish baseline data, and to fulfill the statutory requirements of the Public Health Service Act. This information will provide the laboratory surveyor an overview of your laboratory's operation, if it is subject to onsite survey. When completing this form, the information submitted should be based on your laboratory's operation (i.e., hours of operation, number of personnel involved in testing). **Note: The CLIA identification number block/line should be left blank as this will be assigned when the application form is processed. Also, if you wish to apply for a Provider Performed Microscopy Procedure (PPMP) certificate, write this in section II of the CMS-116.**

Upon return of the completed Form CMS-116 to the State Agency, a fee remittance coupon will be issued to you indicating your CLIA identification number, the amount due for the certificate and, if applicable, the compliance fee for your survey. Based on the information you provide about your laboratory, the appropriate certificate will be issued to you on receipt of full payment.

(Name)

Page 2

(Date)

Also, enclosed is the Disclosure of Ownership and Control Interest Statement (Form CMS-1513) which must be completed within 30 days. Please return both forms to the State agency listed below. If you have any questions regarding the completion of these forms you should contact the state agency listed below:

(State Agency Address)

Sincerely yours,

Enclosures