

**EXHIBIT 110**

**COMPLIANCE WARNING LETTER FAILURE TO APPLY FOR  
CERTIFICATE**

**(Date)**

Name of Laboratory Director

Name of Facility

Street Address

City, State, ZIP Code

CERTIFIED MAIL -- RETURN RECEIPT REQUESTED

Dear **(Laboratory Director Name)**:

It has come to the attention of the Centers for Medicare & Medicaid Services (CMS) that your laboratory is performing laboratory testing without the appropriate CLIA certificate.

Section 353(b) of the law states that “No person may solicit or accept materials derived from the human body for laboratory examination or other procedure unless there is in effect for the laboratory a certificate issued by the Secretary under this section applicable to the category of examinations or procedures which includes such examination or procedure.” Therefore, you are in violation of CLIA.

Laboratory testing must be discontinued immediately and remain discontinued until the laboratory is properly certified as stipulated by CLIA. A written response to this letter is required within 15 days after certified receipt date. Failure to respond will result in further investigation.

Your response should be directed to:

**(Name)**

**(Street Address)**

**(City, State, ZIP code)**

**(Attention)**

For immediate response you may call **(phone number and contact name)**.

Sincerely yours,