



7500 Security Boulevard
Baltimore, MD 21244-1850

APR 9 2002

Rankine Forrester
Intoximeters, Incorporated
8110 Lackland Road
St. Louis, Missouri 63114

Dear Ms. Forrester:

This is in response to your e-mail inquiry concerning whether breath testing is regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

For the purposes of CLIA, laboratory testing is testing that is done for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body 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, human beings. Currently, breath testing (including alcohol breath testing) is not encompassed under this definition in the CLIA regulations and, therefore, is not subject to the provisions of CLIA.

Should it be determined in the future that breath testing is subject to CLIA, proper notice will be provided and an opportunity for public comment will be given before the determination is final.

If I can be of further assistance, please do not hesitate to contact me.

Sincerely yours,

A handwritten signature in black ink that reads "Judith A. Yost".

Judith A. Yost
Director
Division of Laboratories and Acute Care Services
Survey and Certification Group
Centers for Medicaid and State Operations