



Center for Clinical Standards and Quality/Survey & Certification Group

July 20, 2017

Betye Bailey
Corporate Training Manager
Intoximeters, Incorporated.
2081 Craig Road
St. Louis, MO 63146

Dear Ms. Bailey:

This is in response to your most recent inquiry regarding a request for an updated letter concerning whether breath testing is regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). It is indeed the case that since April 9, 2002, the date of CMS' original letter, that there have been no changes to the CLIA regulations regarding breath testing.

For the purpose 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 in the Federal Register 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,

A handwritten signature in black ink that reads "Karen W. Dyer". The signature is fluid and cursive.

Karen Dyer, MT (ASCP), DLM
Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality