Clinical Laboratory Improvement Amendments of 1988

Changes resulting from the Food and Drug Administration Modernization Act (FDMA) of 1997

Link to the FDMA 97: http://www.gpo.gov/fdsys/pkg/PLAW-105publ115/pdf/PLAW-105publ115.pdf
FDMA 97 Citation: 111 Stat. 2324, Public Law 105–115, Sec. 123(h)

The FDA Modernization Act of 1997 (FDMA) amended CLIA 1988's criteria for waived testing as stated in section 353(d)(3) of the Public Health Service Act [42 U.S.C. 263a(d)(3)] as follows:

> (3) EXAMINATIONS AND PROCEDURES.—The examinations and procedures identified in paragraph (2) are ~~simple~~ laboratory examinations and procedures that have been approved by the Food and Drug Administration for home use or that ~~which~~, as determined by the Secretary, are simple laboratory examinations and procedures that have an insignificant risk of an erroneous result, including those ~~which~~ that—
>
> > ~~(A) have been approved by the Food and Drug Administration for home use,~~
> > (~~B~~ A) employ methodologies that are so simple and accurate as to render the likelihood of erroneous results by the user negligible, or
> > (~~C~~ B) the Secretary has determined pose no reasonable risk of harm to the patient if, performed incorrectly.

Note that this document is provided as a convenience and includes excerpts from the full CLIA '88 Law to demonstrate the changes. This document does not represent the full context or intent of the law. To view CLIA '88 in its entirety, please search for the current version of 42 USC 263a on the U.S. Government Printing Office (GPO) website.

Also, the December 4, 2012 TEST Act revisions may not be reflected in 42 USC 263a on the GPO's site prior to the edition of the United States Code pending publication in October 2013.

Link to the U.S. Government Printing Office search: http://www.gpo.gov/fdsys/search/advanced/advsearchpage.action

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