

Yale University

Marie Louise Landry, M.D.
Professor
Department of Laboratory Medicine
School of Medicine
333 Cedar Street
P.O. Box 208035
New Haven, Connecticut 06520-8035

Dockets Management Branch (HFA-305)
Docket No. 01D-0044
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

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Telephone: 203 688-3475

May 30, 2001

SUBJ: Comments on CLIA Waiver Guidance for CLIA 1988

To Whom It May Concern:

I am writing concerning the CLIA Waiver Guidance for CLIA 1988. I understand that the deadline for comments is May 30, 2001. However, I just became aware of this document yesterday, May 29. Unfortunately, most laboratorians are not aware of this document.

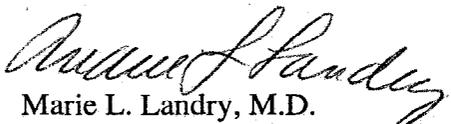
From my brief perusal of this document, I am most concerned about the lack of concern for **specimen adequacy**. This is primarily a problem, in my experience, for non-blood samples, such as upper respiratory tract samples. We and others, who have used rapid membrane EIA tests for RSV and influenza, have found that **sample collection technique and the age of the patient make a tremendous difference in the sensitivity of the test**.

The data currently given in the manufacturer's package insert does NOT reflect the reality of untrained personnel collecting samples. Studies abound in the literature and in meeting abstracts that document that manufacturer's claims for test sensitivity do not hold up (recent examples are the rapid influenza tests). With implementation of the CLIA Waiver Guidance as stated, this situation is likely to worsen. Data should be collected in this regard and package inserts should accurately reflect the reality.

Lastly, I feel very strongly that Laboratorians should be made aware of these changes. Is it possible for the FDA to notify their professional organizations? Otherwise, there is no opportunity for the FDA to obtain feedback, except from industry.

Thank you for your consideration of these comments.

Sincerely,



Marie L. Landry, M.D.
Director, Clinical Virology Laboratory

Fax: 203-688-8177
email: marie.landry@yale.edu

cc. S. Gutman

01D-0044

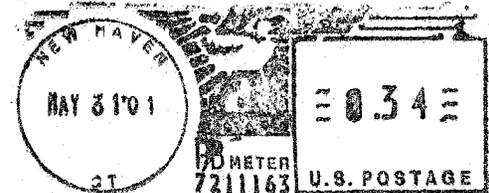
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**YALE-NEW HAVEN
HOSPITAL**

20 York Street
New Haven, CT 06504

Marie L. Landry, M.D.
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DOCKET No. 01D-0044
FOOD AND DRUG ADMINISTRATION
5630 FISHERS LANE RM 1061
ROCKVILLE MD 20852

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