

HFI - 3/44

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

750

Refer to: 1177865

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4012

December 9, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ira D. Godwin, M.D., Director of Laboratories
American Medical Laboratories, Incorporated
14225 Newbrook Drive
Chantilly, Virginia 22021-0841

Dear Dr. Godwin:

During an inspection of your laboratory facility conducted by the Food and Drug Administration from August 19 to October 9, 1997, our investigator documented violations of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act and Title 21, Code of Federal Regulations, Parts 600-680. The following deviations were found:

HIV-1 Western Blot

1. Failure to establish and implement scientifically sound and appropriate specifications, standards, and test procedures to assure that blood components are safe, pure, potent, and effective. The American Medical Laboratories' (AML) procedure is to repeat Western Blots on samples testing indeterminate and to change the original result if the retest is negative.
2. Failure to record all information required by the Western Blot HIV-1 Bio-Rad Norvapath testing instructions. The worksheet used by AML to record test data does not require all data.
3. Failure to maintain Western Blot test records concurrently with the performance of each significant step. For example, when more than one Western Blot is performed, only the bands for the final Western Blot are recorded; there is no record of the bands analyzed for the initial Western Blot.

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HBsAg Testing

4. Failure to follow the Confirmatory Neutralization Test for Detection of Hepatitis B Surface Antigen (HBsAg) testing protocol. An explanation is required for repeat testing, but retests were completed without explanation.
5. Failure to maintain and follow Standard Operating Procedures, as the procedure, "Confirmatory Neutralization Test for Detection of Hepatitis B Surface Antigen (HBsAg)," does not describe the use or purpose of the external "VIROTROL" control used as a quality control measure for each test.

We request that you notify all parties that submitted donor samples to your firm for anti-HIV-1 Western Blot confirmatory testing that were initially found to be "indeterminate," but were retested and reported as "negative" between April and August 1997, that the test results were changed.

The above listed violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

We acknowledge receipt of your December 3, 1997 response to the inspection and are in the process of evaluating the corrective actions outlined.

You should take prompt measures to correct these deviations. Failure to do so may result in regulatory action without further notice.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for delay and the time within which the corrections will be completed.

Your response should be sent to Mr. Wiley T. Williamson III, Compliance Officer, Food and Drug Administration, 900 Madison Avenue, Baltimore, Maryland 21201.

Sincerely,



Elaine Knowles Cole
Director, Baltimore District

Dr. Ira D. Godwin
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cc: Ms. Judith Yost
Health Care Financing Administration
Division of Outcomes and Improvements
7500 Security Boulevard
52-11-07
Baltimore, MD 21244-1850