



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Mid-Atlantic Region D1282B

Telephone (201) 331-2909

March 24, 1997

Food and Drug Administration  
Waterview Corporate Center  
10 Waterview Blvd., 3rd Floor  
Parsippany, NJ 07054

**WARNING LETTER**

Dr. Harold Paz  
Dean, RWJ Medical School  
Clinical Academic Bldg.  
125 Paterson Street  
New Brunswick, New Jersey 08901

**File No: 97-NWJ-26**

Dear Dr. Paz:

During an inspection of University Diagnostic Laboratories, located at 675 Hoes Lane, Piscataway, New Jersey on February 5, 6, 10 & 18, 1997, Investigators from this office documented violations of Section 501(a)(2)(B) of the Federal Food & Drug and Cosmetic Act and Title 21, Code of Federal Regulation (CFR), Parts 600-680, as they relate to testing blood components. These deviations were cited on a FDA483 List of Inspectional Observations issued to responsible management at UDL on February 18, 1997.

The significant observations are as follows:

1) The Quality Assurance Program is deficient in that:

- there is no assurance that a designated director is exercising control over personnel and procedures in all matters relating to compliance.
- there is no documentation of a quality assurance review of quality control records, including assay failures and equipment records.
- technologists routinely review and sign-off on their own testing data records, without QA supervisory review.
- incident reports regarding discrepant test results, were found to be lacking or incomplete.

2) Deviations were noted during testing operations, as follows:

- the technologist did not utilize a system to correlate test strip number to sample ID, that would prevent the potential mixup of samples observed during the pipetting operation for the [REDACTED] assay.

**RELEASE**

○ the technologist failed to follow the [REDACTED] test kit insert, in that, before reading, strips were routinely dried for 15 minutes, rather than 30 minutes.

○ test results were added or modified to the DMS status report without supervisory documentation or review. For example, there were two HIV1/2 EIA results found added to the report one day after the actual test.

○ only the final interpretation of test results are sent to the contract blood banks, rather than individual assay results, which indicate if repeat testing was performed for initially reactive results.

○ initially reactive results are routinely tested in singlet when there is insufficient quantity to conduct repeat testing of samples in duplicate. The practice of accepting insufficient sample volumes has not been addressed by the lab.

3) Numerous procedural deficiencies were noted, which include:

○ lack of supervisory review and approval for several written procedures.

○ lack of a written procedure for handling the investigation and documentation of incidents.

○ lack of written procedures for the review of test kit inserts and storage.

○ lack of written procedures for alerting the contract blood bank of testing errors or questionable results.

○ written procedures allow for test interpretations of "borderline" and "weak reactive", these interpretations are not defined as reportable results in the EIA test kit inserts.

○ the procedure for refrigerator temperature is not consistent with the test kit insert instructions for reagent storage.

○ an obsolete procedure was found in the current manual.

4) Failure to follow established SOPs, for example:

- samples are tested and results are reported for samples that do not have requisition slips.
- examples were noted of record changes that were obliterated with black marker or whited out.

The above deviations 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 federal regulations, with regard to blood testing and quality assurance activities.

You should take prompt measure to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice.

We have not yet received a written response to the FDA483 Inspectional Observations issued to University Diagnostics Laboratory on February 18, 1997. This letter is sent to your attention as the most responsible individual for overall activities at this testing laboratory. At the close of the inspection, an intent to voluntarily register with the FDA was expressed by UDL's management, in order to receive FDA memorandum and guidelines regarding Quality Assurance Activities. You may contact our office directly at (201) 331-2909 if you feel a meeting is needed to provide further clarification of FDA guidelines and regulations as they relate to testing facilities.

Please 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, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the timeframe within which the corrective measures will be implemented. Also include copies of any available documentation demonstrating that corrections have been made.

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Your reply should be directed to the New Jersey District Office of the Food & Drug Administration, 10 Waterview Blvd., 3rd Floor, Parsippany, New Jersey 07054, Attn: Mercedes B. Mota, Compliance Officer.

Sincerely,



RAY ABRAHAMS  
Acting District Director  
New Jersey District

CERTIFIED MAIL -  
RETURN RECEIPT REQUESTED

MBM:np

cc: Robert Trelstad, MD  
Chairman, Pathology  
Medical Education Bldg. Rm 204  
1 Robert Wood Johnson Place  
New Brunswick, New Jersey 08901

