



Dallas District  
4040 North Central Expressway  
Dallas, Texas 75204-3145

October 10, 2002

**Ref: 2003-DAL-WL-02**

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURNED RECEIPT REQUESTED**

Mr. Robert H. Collins, Owner and President  
Eagle Diagnostics, Inc.  
P.O. Box 1237  
DeSoto, Texas 75123

Dear Mr. Collins:

During an inspection of your establishment located in Cedar Hill, Texas, on April 8, 9, 10, 11, and 16, 2002, our investigators determined that your firm repackages and/or relabels many in vitro diagnostic devices shipped in interstate commerce with packaging and labeling bearing your firm's name. In vitro diagnostic devices are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above stated inspection revealed that these devices are adulterated under section 501(h) of the Act, in that the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements for medical devices which are set forth in the Quality System regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to maintain device history records to demonstrate the devices are manufactured in accordance with the device master record as required by 21 CFR 820.184. For example, your firm could not provide production records for the repackaging of Nitroprusside [FDA 483 Item 6].
2. Failure to establish and maintain device acceptance procedures to ensure that finished devices are not released for distribution until all activities required in the device master record are completed as required by 21 CFR 820.80(d). For example, your firm released Glyco Calibrator lot # 062791 and Glyco Unitest Set lot #012216 without completing the required quality control testing [FDA 483 Item 1].

3. Failure to establish and maintain production and process control procedures to ensure that devices conform to their specifications as required by 21 CFR 820.70(a). For example, your firm failed to establish specifications or parameters for the mixing process used in the repackaging of the Glycohemoglobin resin [FDA 483 Item 2].
4. Failure to establish and maintain environmental control procedures to prevent an adverse effect on product quality as required by 21 CFR 820.70(c). For example, your firm repackages powder in vitro products in a humidity-controlled room to prevent clumpiness in the final product due to excess humidity. Your firm was unable to provide written procedures establishing the specific environmental requirements for this room [FDA 483 Item 5].
5. Failure to establish and maintain procedures for acceptance of incoming product as required by 21 CFR 820.80(b). For example, your firm could not provide records or documentation showing your firm's receipt, acceptance or rejection, and approval of raw materials used for repackaging the in vitro devices [FDA 483 Items 8 and 9].
6. Failure to establish and maintain purchasing data that clearly describe or reference the specified requirements, including quality requirements, for purchased products as required by 21 CFR 820.50(b). Your firm could not provide purchasing records documenting your required specifications for purchased materials [FDA 483 Item 10].
7. Failure to evaluate potential suppliers or vendors of purchased materials to ensure that quality requirements will be met and to document such evaluations as required by 21 CFR 820.50(a). Your firm could not provide records establishing and documenting that you evaluated your suppliers' and vendors' ability to meet specified requirements. [FDA 483 Item 7].
8. Failure to establish and maintain procedures for verifying or validating changes to device design specifications and approval of design changes before their implementation as required by 21 CFR 820.70(b). For example, you stored the Uric Acid (TPTZ) Reagent and Calcium Reagent Tests at a lower temperature range than their OEM labeled specification [FDA 483 Item 4].

Page 3 – Mr. Robert H. Collins, Owner and President  
Eagle Diagnostics, Inc.  
October 10, 2002

9. Failure to establish and maintain procedures to ensure that manufacturing equipment is routinely calibrated as required by 21 CFR 820.72(a). For example, your firm failed to calibrate the spectrophotometer used in the quality control testing of repackaged in vitro devices according to the written scheduled interval [FDA 483 Item 11].

The inspection also revealed that most of your devices are misbranded under section 502(o) of the Act for failure to file a premarket notification submission in accordance with section 510(k) of the Act.<sup>1</sup> In addition, the absence of valid marketing clearance (i.e., 510(k) clearance) from FDA automatically renders these products Class III devices under section 513(f) of the Act. Class III devices may not be introduced into interstate commerce unless you first obtain either premarket approval (PMA) from FDA pursuant to section 515(a) of the Act or an approved investigational device exemption (IDE) under section 520(g). Because an approved PMA or an approved IDE does not cover your devices (excluding the two 510(k) exempt devices), they are adulterated within the meaning of section 501(f)(1)(B) of the Act. Distribution in interstate commerce of misbranded or adulterated devices is prohibited by law under section 301 of the Act.

Your firm's product catalog lists a number of unapproved devices, including specialty quick tests for HIV and HBsAg as intended for export only. Our review of documentation collected concerning these devices during the inspection reveals that they fail to meet the conditions for export under sections 801 or 802 of the Act. For example, sales records obtained from your firm indicate that these devices have been sold or offered for sale within the United States and therefore fail to meet the requirement set forth at section 801(e)(1)(D). Your records also indicate that the repackaged product label for the HBsAg quick test was not labeled as intended for export as required by section 801(e)(1)(C). Unapproved devices that fail to comply with the requirements of section 801(e)(1) may not lawfully be exported under section 801 or 802 of the Act.

Additionally, your registration needs to be updated to include the fact that you are a manufacturer as required by 21 CFR 807.20.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence to all applicable requirements of the

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<sup>1</sup> Two of your devices, the GPT and GGT reagent sets, are exempt from premarket notification (i.e., 510(k)) requirement. In addition, you should know that two others, your HIV and Hepatitis test kits, could not be found to be "substantially equivalent" within the meaning of Section 513(i) of the Act and therefore require approved PMAs before marketing.

Page 4 – Mr. Robert H. Collins, Owner and President  
Eagle Diagnostics, Inc.  
October 10, 2002

Act and regulations. The specific violations noted in this letter and in the FDA 483 issued to you at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA.

Federal agencies are advised of the issuance of all Warning Letters involving devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for class III devices to which the QS/GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please provide this office in writing within 15 working days of receipt of this letter a report 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 in the future. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your reply should be directed to Thao Ta, Compliance Officer, at the above letterhead address.

Sincerely yours,

  
Michael A. Chappell  
Dallas District Director