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The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Division of Health Care Quality
Clinical Laboratory Program
99 Chauncy Street, 2nd Floor, Boston, MA 02111
(617) 753-8439/8438 (617) 753-8240 - Fax

February 22,2010

IMPORTANT NOTICE – ACTION NECESSARY

Via facsimile to (508)226-2218 and first class mail. *(Confirmation of successful transmission of facsimile constitutes proof of receipt.)*

Marcus Gordon, MD,
Laboratory Director
Four Women Health Services, LLC,
150 Emory Street
Attleboro, MA 02703

CLIA # 22D0945040

RE: CONDITION-LEVEL DEFICIENCIES

Dear Director/Owner(s):

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, it must comply with all CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. § 263a) and 42 Code of Federal Regulations, Part 493 (42 C.F.R. § 493). Federal regulations require onsite surveys to determine whether or not a laboratory is in compliance with the applicable regulations. Compliance with these regulations is a condition of certification for the CLIA program.

The Clinical Laboratory Program conducted Clia Recert survey of your laboratory that was completed on February 9, 2010.

As a result of the survey, it was determined that your facility is not in compliance with all of the Conditions required for certification in the CLIA program. Specifically, the following Conditions were not met.

D2000 - 42 C.F.R. § 493.801 Condition:	Enrollment and testing of [proficiency testing] samples;
D6000 - 42 C.F.R. § 493.1403 Condition:	Laboratories performing moderate complexity testing; laboratory director;

In addition, other standards were also found to be not met. Enclosed is Form CMS-2567, Statement of Deficiencies, listing all the deficiencies found during the survey.

Laboratories that do not meet the Condition-level requirements of CLIA may not be certified to perform laboratory testing under the CLIA program. You must take steps to bring any unmet Conditions into compliance immediately.

You are directed to submit a credible allegation of compliance and acceptable evidence of correction for the deficiencies cited. Please document your allegation of compliance using the enclosed CMS-2567, Statement of Deficiencies, in the columns labeled “Provider Plan of Correction” and “Completion Date” located on the right side of the form, keying your responses to the deficiencies on the left. The laboratory director must sign, date and return the completed CMS-2567 documented with a credible allegation of compliance to our office WITHIN 10 DAYS FROM RECEIPT of this notice. You must also submit documented evidence that verifies that the corrections were made. We may conduct a follow-up onsite survey in approximately 30-45 days to verify the corrections if we find your allegation of compliance to be credible and the submitted evidence to be acceptable. If your laboratory does not submit a credible allegation of compliance and acceptable evidence of correction, we will not conduct a follow-up survey. (Your allegation of compliance will be included in the public record of the inspection.)

A credible allegation of compliance is a statement or documentation that is:

1) Made by a representative of a laboratory with a history of having maintained a commitment to compliance and taking corrective action when required;
2) Realistic in terms of the possibility of the corrective action being accomplished between the date of the survey and the date of the allegation; and
3) Indicates resolution of the problems.

For your information, acceptable evidence of correction must include:

1) Documentation showing what corrective action(s) have been taken for patients found to have been affected by the deficient practice;
2) How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) has been taken;
3) What measure has been put into place or what systemic changes you have made to ensure that the deficient practice does not recur, and
4) How the corrective action(s) are being monitored to ensure the deficient practice does not recur.

If you do not submit a credible allegation of compliance and acceptable evidence of correction, or if you submit an allegation of compliance that is determined to be credible but are found to be still out of compliance with any CLIA Condition-level requirements at the time of the follow-up visit, the Clinical Laboratory Program will recommend to the Boston Regional Office of the Centers for Medicare & Medicaid Services (CMS) that sanctions be taken against your laboratory's CLIA certificate. These may include alternative sanctions (Civil Money Penalty of up to $3,000 per day of noncompliance per 42 C.F.R. § 493.1834, Directed Plan of Correction per 42 C.F.R. § 493.1832, State Onsite Monitoring per 42 C.F.R. § 493.1836) and principal sanctions (suspension, limitation and/or revocation of your laboratory's CLIA certificate and cancellation of your laboratory's approval for Medicare payments per 42 C.F.R. § 493.1814).

Please note that the routine survey takes an overview of the laboratory through random sampling. By its nature, the routine survey may not find every violation that the laboratory may have committed. It remains

the responsibility of the laboratory and its director to ensure that the laboratory is at all times following all CLIA requirements, to identify any problems in the laboratory and take corrective action specific to the problems, and to institute appropriate quality assessment measures to ensure that the deficient practices do not recur.

In addition to the routine CLIA certification surveys, announced or unannounced investigations/ surveys may be conducted by the State agency at any time to address complaints or other noncompliance issues. These investigations/surveys may well identify violations that may not have surfaced during a routine survey using random sampling, but for which the laboratory and its director will still be held responsible.

If you have questions regarding this letter, please contact me at (617) 753-8438 or (617) 753-8439.

Sincerely,

Roberta Teixeira
Director, Clinical laboratory Program

Enclosure: CMS-2567, Statement of Deficiencies