The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Division of Health Care Facility Licensure and Certification
99 Chauncy Street, Boston, MA 02111

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Governor

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Lieutenant Governor

MARYLOU SUDDERS
Secretary

EILEEN M. SULLIVAN
Acting Commissioner

Tel: 617-753-8000
www.mass.gov/dph

January 20, 2015

IMPORTANT NOTICE – ACTION NECESSARY

Via facsimile to (508) 226-2218 and
CERTIFIED MAIL - RETURN RECEIPT REQUESTED.
(Confirmation of successful transmission of facsimile constitutes proof of receipt.)

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

RE: CLIA NUMBER
22D0945040

RE: CONDITION-LEVEL DEFICIENCIES WITH REGARD TO PROFICIENCY TESTING PERFORMANCE

Dear Laboratory Director:

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.

As a result of proficiency testing review of your facility, 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:

D2016 – 42 C.F.R. § 493.803 Condition: Successful participation [proficiency testing]; and,
D9999 – 42 C.F.R. § 493.857 Condition: Immunohematology

Based on a review of proficiency testing performance, it was determined unsuccessful participation has been noted in the following area(s):

TESTING EVENTS	PROGRAM	ANALYTE SPECIALTY OR SUBSPECIALTY	YOUR SCORE
2, 2014	AAB	Immunohematology	0% Results Not Reported
3, 2014	AAB	Immunohematology	60%
2, 2014	AAB	ABO Group/Rh Typing (Non Tranfusion)	0% Reults Not Reported
3, 2014	AAB	ABO Group/Rh Typing (Non Tranfusion)	60%

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 review.

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.

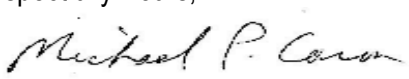
CLIA regulations at 42 C.F.R. § 493.1838 allow a laboratory at the first occurrence of unsuccessful PT performance to undertake training of its personnel, or obtain necessary technical assistance, or both, if appropriate to the circumstances. If your laboratory determines that training/technical assistance is the appropriate corrective action, evidence must be submitted to document that the training and/or technical assistance have been undertaken and were effective in correcting the problems that caused the unsuccessful PT performance. In particular, the evidence must include documentation that your laboratory has taken action to correct actual or potential patient outcome during the period of PT failure. See the requirements for acceptable evidence of correction above.

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).

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

Respectfully Yours,



Michael P. Caron, MS, MT(ASCP)
Health Care Facility Surveyor

Enclosure: CMS-2567, Statement of Deficiencies

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