



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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July 7, 2015

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

Marcus Gordon, M.D., Director
Four Women Health Services LLC
150 Emory Street
Attleboro, MA 02703

CLIA # 22D0945040

RE: ALLEGATION OF COMPLIANCE CREDIBLE AND EVIDENCE OF CORRECTION
ACCEPTABLE

Dear Director:

By letter dated January 20, 2015, the Clinical Laboratory Program notified you that your laboratory was not in compliance with the Conditions of successful participation in proficiency testing (PT) and Laboratory Director based on unsatisfactory performance in PT for for the following testing events:

- 2,2014 AAB Immunoematology**
- 3,2014 AAB Immunoematology**
- 2,2014 AAB ABO Group/Rh Typing (Non Transfusion)**
- 3,2014 AAB ABO Group/Rh Typing (Non Transfusion).**

In the letter, we requested that you submit a credible allegation of compliance and acceptance evidence of correction. We received your response on February 3, 2015, and have determined that your allegation of compliance is credible and evidence of correction is acceptable.

We caution your laboratory to maintain compliance with all CLIA requirements for proficiency testing. If it is discovered that your allegation of compliance was not implemented or that compliance was not maintained, the Clinical Laboratory Program will refer the case to the Regional Office of the Centers for Medicare & Medicaid Services (CMS) for appropriate action, and recommend that sanctions be

taken against your laboratory's CLIA certificate.

Any future proficiency testing failure that results in a subsequent occurrence of unsuccessful participation in proficiency testing will be basis for such referral to the CMS Regional Office to initiate sanction actions against your laboratory's CLIA certificate. These sanctions may include alternative sanctions of a Directed Plan of Correction, Civil Money Penalty and suspension of the laboratory's approval to receive Medicare payments as well as principal sanctions of suspension, limitation or ~~revocation of your laboratory's CLIA certificate and cancellation of the laboratory's approval to receive Medicare payments.~~

If you have questions regarding this letter, please contact me at (617)753-7307 or Pamela.Waksmonski@state.ma.us.

Sincerely,



Pamela Waksmonski, MS, MT(ASCP)
Manager, Clinical Laboratory Program

cc: CMS Regional Office

Facility File