DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
JFK Federal Building, Government Center
Room 2350
Boston, MA 02203

CENTERS FOR MEDICARE & MEDICAID SERVICES

Northeast Division of Survey & Certification

IMPORTANT NOTICE - ACTION NECESSARY

Via certified mail.

August 25, 2015

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

CLIA number: 22D0945040

RE: PROPOSED SANCTIONS DUE TO SUBSEQUENT OCCURRENCE OF UNSUCCESSFUL PARTICIPATION IN PROFICIENCY TESTING - **IMPOSITION NOTICE TO FOLLOW IF PROPOSED SANCTIONS ARE IMPOSED**

Dear Dr. Gordon:

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. Part 493). Compliance with these regulations is a requirement for certification for the CLIA program.

Subpart H of 42 C.F.R Part 493 requires each laboratory certified to test specimens under the CLIA regulations to successfully participate in an approved proficiency testing program. The CLIA regulations at 42 C.F.R. § 493.2 define, as set out in Subpart H, unsuccessful proficiency testing performance as failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for two consecutive or two out of three consecutive testing events.

Determination of Non-Compliance: Finding of Unsuccessful Participation in Proficiency Testing - Subsequent Occurrence

Evidence obtained by the Bureau of Health Care Safety & Quality, Massachusetts State Agency (SA) during a desk review conducted on May 21, 2015, of proficiency testing results submitted to CLIA from your laboratory's proficiency testing program shows your laboratory has a repeat history of unsatisfactory proficiency testing performance for the tests and events listed below

which constitutes a subsequent occurrence of unsuccessful participation in proficiency testing for these tests:

Testing Event PT Provider Test Score

TESTING EVENTS	PROGRAM	ANALYTE SPECIALTY OR SUBSPECIALTY	YOUR SCORE
2, 2014	AAB	D(RhO)	0%
3, 2014	AAB	D(RhO)	60%
1, 2015	AAB	D(RhO)	80%

Based on the repeat proficiency testing failures listed above, your laboratory is not in compliance with two CLIA Conditions. The enclosed Form CMS-2567, Statement of Deficiencies, specifically documents the laboratory's failure to meet the Condition-level requirements at:

- D2016 - 42 C.F.R. § 493.803 Condition: Successful participation [proficiency testing]; and
- D6076 - 42 C.F.R. § 493.1441 Condition: Laboratories performing high complexity testing; laboratory director.

In addition, other standards were found to be not met.

Proposed Sanctions Based on Unsuccessful Participation in Proficiency Testing - Subsequent Occurrence

Pursuant to 42 C.F.R. §§ 493.1804(b)(1)(ii), 493.1806(a), and 493.1840(a)(3), we propose to take sanction actions against the laboratory's CLIA certificate based on Condition-level non-compliance as evidenced by:

(1) The repeat history of proficiency testing failures in the specialty of Immunohematology, for the analyte D(RhO), which constitutes a subsequent occurrence of unsuccessful participation in proficiency testing; and
(2) The laboratory director's failure to fulfill his responsibility for monitoring proficiency testing to ensure that the laboratory is in compliance with the CLIA Condition of successful participation in proficiency testing.

We propose to take the following sanction actions against the laboratory's CLIA certificate:

• 42 C.F.R. §§ 493.803(b), 493.1804(b)(1)(ii), 493.1806, and 493.1840(a)(3) - Principal Sanction: **Limitation** of the laboratory's CLIA certificate for the specialty of Immunohematology for not less than six months effective September 9, 2015. When a laboratory's CLIA certificate is limited in a specific specialty, the laboratory will not be permitted to perform any patient testing in that specialty.

NOTE: The laboratory may continue to perform parallel testing on patient specimens in the specialty of Immunohematology if needed to implement corrective actions, however, the laboratory may not report any patient test results in the specialty of Immunohematology during the period when its CLIA certificate is limited in the specialty of Immunohematology.

The laboratory has sixty (60) days in which to appeal the determination to limit its certificate in the specialty of Immunohematology. If the laboratory chooses not to file an appeal, limitation of its CLIA certificate in the specialty of Immunohematology will become effective September 9, 2015. If a timely hearing request is received, limitation of the laboratory's CLIA certificate in the specialty of Immunohematology will be effective with the date of the administrative hearing decision, if our determination of non-compliance is upheld.

As noted below, pursuant to 42 C.F.R. §§ 493.1840(a)(4) and 493.1844(d)(2)(ii)(B), limitation of the laboratory's CLIA certificate will not be delayed even if a hearing is filed if the laboratory fails to comply with the terms of the Directed Plan of Correction (see proposed sanction of a Directed Plan of Correction below).

• 42 C.F.R. §§ 493.1804(b)(1)(ii), 493.1804(b)(2), 493.1806(c)(1), 493.1832, and 493.1844(h)(2) - Alternative Sanction: **Directed Plan of Correction** effective September 9, 2015. If this sanction is imposed, the laboratory is directed to

1) address any actual or potential negative patient outcome during the period of unsuccessful proficiency testing performance for the specialty of Immunohematology and submit acceptable evidence that this has been done within ten (10) calendar days from the date of the notice of imposition;

2) demonstrate that the laboratory has established an effective oversight mechanism to prevent recurrences of proficiency testing failure for all testing including testing in the specialty of Immunohematology and submit acceptable evidence that such a mechanism has been implemented within ten (10) calendar days from the date of the notice of imposition; and

3) demonstrate satisfactory performance in two consecutive proficiency testing events for the specialty of Immunohematology before the limitation of the laboratory's certificate in the specialty of Immunohematology can be lifted. The laboratory may obtain the two consecutive proficiency testing events from any proficiency testing program approved by CMS for the calendar year.

Acceptable evidence of correction to be submitted to meet the requirements of the Directed Plan 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) have been taken;
3) What measure has been put into place or what systemic changes have been 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.

Please note that pursuant to 42 C.F.R. §§ 493.1840(a)(4) and 493.1844(d)(2)(ii)(B), if the laboratory fails to comply with the terms of the Directed Plan of Correction above, it will constitute failure to comply with a reasonable request from CMS for information and work on materials necessary to determine continued eligibility for its CLIA certificate or continued compliance with performance standards set by CMS, and will result in the limitation taking effect September 9, 2015, regardless of whether a hearing is filed. In addition, pursuant to 42 C.F.R. § 493.1840(a)(7), failure to comply with alternative sanctions is a basis for limitation, suspension, or revocation of any type of CLIA certificate.

* We note that on January 20, 2015, the SA notified your laboratory of a first occurrence of unsuccessful participation in proficiency testing under the specialty of Immunohematology, for the analyte ABO Group/Rh Typing, based on unsatisfactory results for the 2014 third event. On February 3, 2015, the SA received your allegation of compliance and evidence of correction which was deemed to be acceptable. The subsequent occurrence of unsuccessful participation in PT, 2015 first event, indicates that the laboratory failed to either implement corrections as alleged or monitor for the effectiveness of its corrective actions.

• 42 C.F.R. §§ 493.1804(b)(1)(ii), 493.1804(b)(2), 493.1807(b), 493.1808(b), 493.1826, 493.1844(d)(1), and 493.1844(h)(2) - Medicare Alternative Sanction: **Suspension of the laboratory's approval to receive Medicare payments** for any services performed in the specialty of Immunohematology effective September 9, 2015.

The laboratory must agree in writing (in return for not having its Medicare approval cancelled immediately) to not charge Medicare beneficiaries or their private insurance carriers for the services for which Medicare payment is suspended, i.e., in the specialty of Immunohematology. Failure to provide this written agreement will result in the cancellation of the laboratory's approval to receive Medicare payment for all laboratory services effective September 9, 2015.

As a consequence of the suspension of the approval to receive Medicare for services performed in specialty of, under section 1902(a)(9)(C) of the Social Security Act and 42 C.F.R. § 440.30(c), payment under the Medicaid program, Title XIX of the Social Security Act, will also no longer be available to the laboratory for all laboratory services performed in the specialty of

Immunohematology. *See* 42 C.F.R. § 440.2(b). Pursuant to 42 C.F.R. § 493.807, the suspension period for Medicare and Medicaid approval for these services is for a period of not less than six months.

Please be advised that the imposition of sanctions cannot be avoided by closure of your laboratory, discontinuation of testing, voluntary withdrawal from the CLIA program, or changes in certificate to a lower level of testing.

Instructions for Sending in Your Response

The laboratory has ten (10) calendar days from the date of this notice, or until September 4, 2015, to submit in writing any evidence or information as to why the proposed sanctions for a subsequent occurrence of unsuccessful participation in proficiency testing for the specialty of Immunohematology and noncompliance with the Conditions of successful participation in proficiency testing and laboratory director should not be imposed. If we do not receive a timely submission or if we determine that the submission is unpersuasive, we will notify you in writing that we will proceed to impose the above-referenced sanctions. We will provide information regarding the laboratory's appeal rights at that time.

All responses, including written evidence as to why the proposed sanctions for a subsequent occurrence of unsuccessful participation in proficiency testing for the specialty of Immunohematology should not be imposed should be sent to:

Paul Miller
Acting, Branch Manager
Centers of Medicare & Medicaid Services
Certification and Enforcement Branch
JFK Federal Building, Room-2350
Boston, MA 02203

If you have any questions, please contact Charles Reynolds at (617) 565-9156 or Bethzaida Rodriguez at (617) 565-2146 of my staff.

Sincerely,

for Paul Miller
Acting, Branch Manager
Certification and Enforcement Branch

Enclosure: Form CMS-2567

cc: Paul DiNatale, Massachusetts SA

Via certified mail, return receipt # **9171082133393968243224**

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	22D0945040	A. BUILDING _____ B. WING _____	R 05/21/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FOUR WOMEN HEALTH SERVICES LLC	150 EMORY STREET ATTLEBORO, MA 02703

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D 000	INITIAL COMMENTS Please refer to Conditions of Participation for Clinical Laboratories 42 CFR 493.	D 000		
D2016	493.803(a)(b)(c) SUCCESSFUL PARTICIPATION Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.	D2016		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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D2016	Continued From page 1 This CONDITION is not met as evidenced by: Based on proficiency testing review for calendar years 2014 and 2015 (three testing events), the laboratory was enrolled in American Association of Bioanalysts proficiency testing program and failed to successfully participate (achieve a score of 100 percent or more) in a proficiency testing program for the D(RhO) typing analyte as evidenced by the following: First Unsuccessful Occurrence: D(RhO) typing analyte: The laboratory achieved a score for D(RhO) typing of zero (0) percent for the second testing event of 2014 (failure to participate - refer to D2155) and a score of sixty (60) percent for the third testing event of 2014 resulting in unsuccessful performance for the analyte and the specialty area of immunohematology. Second Unsuccessful Occurrence: D(RhO) typing analyte: The laboratory achieved a score of 60 percent for the third testing event of 2014 and a score of 80 percent for the first testing event of 2015 resulting in the second unsuccessful performance for the analyte and the specialty area of immunohematology. (Refer to D2162 and D2163). Based on this evidence the laboratory failed to undertake the appropriate training and/or technical assistance necessary to correct the problem of unsuccessful proficiency testing performance for the D(RhO) typing analyte.	D2016		
D2153	483.857(a) ABO GROUP AND D(RHO) TYPING	D2153		

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D2153	Continued From page 2 Failure to attain a score of at least 100 percent of acceptable responses for each analyte or test in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on record review of calendar years 2014 and 2015 proficiency testing results (three testing events), the laboratory was enrolled in American Association of Bioanalysts proficiency testing program and failed to attain a score of at least 100 percent for each analyte leading to unsatisfactory performance and two unsuccessful performances for the same analyte (refer to D2016). The laboratory received a testing score for the D(RhO) typing analyte of sixty (60) percent for the third testing event of 2014 resulting in unsatisfactory performance for the testing event. The laboratory subsequently received a testing score for the D(RhO) typing analyte of eighty (80) percent for the first testing event of 2015 resulting in unsatisfactory performance for the testing event	D2153		
D2154	493.859(b) ABO GROUP AND D(RHO) TYPING Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on record review of calendar year 2014 proficiency testing results (three testing events), the laboratory was enrolled in American Association of Bioanalysts proficiency testing program and failed to attain an overall testing	D2154		

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D2154	Continued From page 3 event score of at least 100 percent for specialty area of immunohematology leading to unsatisfactory performance resulting in a second unsuccessful performance for the specialty area of Immunohematology. The laboratory received a testing score for immunohematology of sixty (60) percent for the third testing event of 2014 resulting in unsatisfactory performance for the testing event. The laboratory achieved a testing score for immunohematology of eighty (80) percent for the first testing event of 2015 resulting in unsatisfactory performance for the testing event.	D2154		
D2155	493.859(c) ABO GROUP AND D(RHO) TYPING Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on proficiency testing review for calendar years 2014 and 2015 (three testing events), the	D2155		

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D2155	Continued From page 4 laboratory was enrolled in American Association of Bioanalysts proficiency testing program and failed to participate in one testing event resulting in unsatisfactory performance and a score of zero (0) percent for the testing events as evidenced by the following: The laboratory failed to participate in the second testing event of 2014 resulting in scores of zero (0) percent for the testing event for the Rh D typing analyte and the specialty area of immunohematology.	D2155		
D2160	493.859(e) ABO GROUP AND D(RHO) TYPING For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. For any unacceptable analyte or unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on calendar years 2014 and 2015 proficiency testing review (three testing events), the laboratory was enrolled in American Association of Bioanalysts proficiency testing program and failed to undertake remedial action in response to unsatisfactory proficiency testing events as evidenced by the following: The laboratory achieved a score for D(RhO) typing of zero (0) percent for the second testing event of 2014 (failure to participate - refer to	D2160		

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D2160	Continued From page 5 D2155) and a score of sixty (60) percent for the third testing event of 2014 resulting in the first unsuccessful performance for the analyte and the specialty area of immunohematology. The laboratory achieved a score for D(RhO) typing of sixty (60) percent for the third testing event of 2014 and a score of eighty (80) percent for the first testing event of 2015 resulting in the second occurrence of unsuccessful performance for the analyte and the specialty area of immunohematology (refer to D2016).	D2160		
D2162	493.859(f) ABO GROUP AND D(RHO) TYPING Failure to achieve satisfactory performance for the same analyte in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on record review of calendar years 2014 and 2015 proficiency testing results (three testing events), the laboratory was enrolled in American Association of Bioanalysts proficiency testing program and failed to attain a testing event score of at least 100 percent for all immunohematology analytes leading to unsuccessful performance. The laboratory received an overall testing score for the D(RhO) typing analyte of zero (0) percent for the second testing event of 2014 (failure to participate- refer to D2155) and a score of sixty (60) percent for the third testing event of 2014 resulting in the first unsuccessful performance for the analyte and the specialty of Immunohematology. The laboratory subsequently obtained a testing	D2162		

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D2162	Continued From page 6 event score for the D(RhO) typing analyte of sixty (60) percent for the third testing event of 2014 and a score of eighty (80) percent for the first testing event of 2015 resulting in the second unsuccessful performance for the analyte and the specialty of Immunohematology.	D2162		
D2163	493.859(g) ABO GROUP AND D(RHO) TYPING Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on record review of calendar years 2014 and 2015 proficiency testing results (three testing events), the laboratory was enrolled in American Association of Bioanalysts proficiency testing program and failed to attain a testing event score of at least 100 percent for the specialty of immunohematology leading to unsuccessful performance. The laboratory received an overall testing event score for immunohematology of zero (0) percent for the second testing event of 2014 (failure to participate- refer to D2155) and a score of sixty (60) percent for the third testing event of 2014 resulting in the first unsuccessful performance for the specialty of immunohematology. The laboratory subsequently obtained a testing event score for immunohematology of sixty (60) percent for the third testing event of 2014 and a score of eighty (80) percent for the first testing event of 2015 resulting in the second unsuccessful performance for the specialty of	D2163		

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D2163	Continued From page 7 immunohematology.	D2163		
D6076	493.1441 LABORATORY DIRECTOR The laboratory must have a director who meets the qualification requirements of §493.1443 of this subpart and provides overall management and direction in accordance with §493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on the deficiencies cited herein, the laboratory director failed to ensure that effective remedial action was instituted in response to unsatisfactory proficiency testing results resulting in the second unsuccessful performance for the D(RhO) typing analyte and the specialty of immunohematology (refer to D2016).	D6076		
{D9999}	CLOSING COMMENTS §493.857 Condition: Immunohematology. The specialty of immunohematology includes four subspecialties for the purposes of proficiency testing: ABO group and D (Rho) typing; unexpected antibody detection; compatibility testing; and antibody identification. This CONDITION is not met as evidenced by: Based on review of proficiency testing records for calendar years 2014 and 2015, the laboratory achieved a score for D(RhO) typing of zero (0) percent for the second testing event of 2014 (failure to participate- refer to D2155) and a score of sixty (60) percent for the third testing event of 2014 resulting in unsuccessful performance for the analyte and the specialty of immunohematology. The laboratory subsequently obtained a testing event score for immunohematology of sixty (60)	{D9999}		

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{D9999}	Continued From page 8 percent for the third testing event of 2014 and a score of eighty (80) percent for the first testing event of 2015 resulting in the second unsuccessful performance for the specialty of immunohematology.	{D9999}		