

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0876799	(X3) Date Survey Completed 08/26/2024
Name of Provider or Supplier Women's Health Services, Pc	Street Address, City, State 111 Harvard Street, Brookline, MA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A CLIA recertification survey was conducted for the Women's Health Services, PC laboratory on 8/26/2024 pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: . Based on proficiency testing (PT) record review and an interview with Testing Person #2 (TP2) on 8/26/2024, the laboratory failed to enroll in an HHS approved PT program for the Rh D typing analyte and the subspecialty area of ABO group & Rh typing specialty area for which it seeks certification as evidenced by the following: The surveyor reviewed the American Association of Bioanalysts (AAB) PT records on 8/26/2024 for calendar year 2024. The review revealed that the laboratory failed to enroll in an HHS approved PT program for the testing under the Rh D typing analyte and the subspecialty area of ABO group & Rh typing for Events M1 and M2 of 2024. TP2 confirmed in an interview on 8/26/2024 at 1:20 P.M. that the laboratory failed to enroll in an HHS approved PT program for all the testing under the Rh D typing analyte and the subspecialty area of ABO group & Rh typing for Events M1 and M2 of 2024. The laboratory performs approximately 392 Rh D Type tests annually. (Refer to D6041) .</p>

D2015

TESTING OF PROFICIENCY TESTING SAMPLES

CFR(s): 493.801(b)(5)(6)

(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:

. Based on proficiency testing (PT) review and interview with Testing Person #2 (TP2) on 8/26/2024, the laboratory failed to document and maintain a copy of all PT records as evidenced by the following: The surveyor reviewed the American Association of Bioanalysts (AAB) PT records for calendar year 2023. The review revealed: 1. The signed attestation statements were not present and signed by the analyst and the laboratory director for AAB Chemistry Module 2023 Event M2 and AAB Non-chemistry Module 2023 Event M2. 2. The coding reports were not present for AAB Chemistry Module 2023 Event M2 and AAB Non-chemistry Module 2023 Event M2. TP2 confirmed in an interview on 8/26/2024 at 1:04 PM that the signed attestation forms and the coding reports were not present for both the 2023 AAB Chemistry and Non-chemistry M2 Events. The laboratory performs 392 Rh D Type tests and 20 Serum hCG tests annually. NOTE: The laboratory ceased Serum hCG testing in 2/2024.

D2100

ENDOCRINOLOGY

CFR(s): 493.843(c)

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 (PT) review and interview with Testing Person #2 (TP2) on 8/26/2024, the laboratory failed to participate in an HHS approved PT program for the serum Human Chorionic Gonadotropin (hCG) analyte and the subspecialty of Endocrinology as evidenced by the following: The surveyor reviewed the American Association of Bioanalysts (AAB) PT records on 8/26/2024 for calendar year 2023. The review revealed that the laboratory was enrolled in the AAB PT program and failed to participate in the AAB Chemistry Module 2023 Event M3 resulting in unsatisfactory performance and a score of zero (0) percent for the testing

event for the serum hCG analyte and the subspecialty of Endocrinology. TP2 confirmed in an interview on 8/26/2024 at 1:04 PM that the laboratory failed to participate in the 2023 AAB Chemistry Module Event M3 for the serum hCG analyte and the subspecialty of Endocrinology. The laboratory performs 20 Serum hCG tests annually. NOTE: The laboratory ceased serum hCG testing in 2/2024.

D2155

ABO GROUP AND D(RHO) TYPING
CFR(s): 493.859(c)

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 (PT) review and interview with Testing Person #2 (TP2) on 8/26/2024, the laboratory failed to participate in an HHS approved PT program for the Rh D typing analyte and the subspecialty area of ABO group & Rh typing as evidenced by the following: The surveyor reviewed the American Association of Bioanalysts (AAB) PT records on 8/26/2024 for calendar year 2023. The review revealed that the laboratory was enrolled in the AAB PT program and failed to participate in the AAB Non-chemistry Module 2023 Event M3 resulting in unsatisfactory performance and a score of zero (0) percent for the testing event for the Rh D typing analyte and the subspecialty area of ABO group & Rh typing. TP2 confirmed in an interview on 8/26/2024 at 1:04 PM that the laboratory failed to participate in the 2023 AAB Non-chemistry Module Event M3 for the Rh D typing analyte and the subspecialty area of ABO group & Rh typing. The laboratory performs 392 Rh D Type tests annually.

D6041

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(3)

(b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;

This STANDARD is not met as evidenced by:
. Based on proficiency testing (PT) record review and an interview with Testing Person #2 (TP2) on 8/26/2024, the Technical Consultant (TC) failed to enroll the laboratory in an HHS approved PT program for the Rh D typing analyte and the subspecialty area of ABO group & Rh typing for which it seeks certification as evidenced by the following: The surveyor reviewed the American Association of Bioanalysts (AAB) PT records on 8/26/2024 for calendar years 2023 and 2024. The review revealed that the TC failed to enroll the laboratory in an HHS approved PT program for the testing under the Rh D typing analyte and the subspecialty area of ABO group & Rh typing for Events M1 and M2 of 2024. TP2 confirmed in an

interview on 8/26/2024 at 1:20 P.M. that the TC failed to enroll the laboratory in an HHS approved PT program for all the testing under the Rh D typing analyte and the subspecialty area of ABO group & Rh typing for Events M1 and M2 of 2024. The laboratory performs approximately 392 Rh D Type tests annually. (Refer to D2000) .