

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0876799	(X3) Date Survey Completed 03/20/2026
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 03/20/2026 pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D2014	<p>TESTING OF PROFICIENCY TESTING SAMPLES</p> <p>(b)(6) 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.</p> <p>This STANDARD is not met as evidenced by: . Based on proficiency testing (PT) record review, procedure review, and an interview with Clinical Director (CD) on 03/20/2026 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 on 03/20/2026 for the following four (4) PT events: AAB Nonchemistry M3 2024 - ABO & Rh Factor AAB-MLE M1 2025 - ABO & Rh Factor AAB-MLE M2 2025 - ABO & Rh Factor AAB-MLE M3 2025 - ABO & Rh Factor The review revealed that the PT final evaluation reports were not reviewed nor signed by the Laboratory Director (LD) or designee for the four (4) AAB PT events. The laboratory's Proficiency Testing Procedure states: "Proficiency Testing results and, if applicable, corrective action report, must be reviewed and signed by the Lab Director or designee even if the testing events are successful." The CD confirmed in an interview on 03/20/2026 at 12:</p>

48 P.M. that the PT final evaluation reports for the four (4) AAB PT events were not reviewed nor signed by LD or designee. The laboratory performs approximately 186 Rh D Type tests annually.