Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 49D0226811	**(X3) Date Survey Completed** 06/04/2024
Name of Provider or Supplier Richmond Medical Center For Women	**Street Address, City, State** 118 N Arthur Ashe Boulevard, Richmond, VA	

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	An announced CLIA recertification survey was conducted at Richmond Medical Center for Women on June 4, 2024 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiency cited is as follows:
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 a review of the laboratory's immunohematology proficiency testing (PT) documentation, procedures, lack of documentation, and interviews, the laboratory failed to retain attestation statement signed by the testing personnel (TP) for one (1) of three (3) events performed in calendar year 2023. Findings include: 1. Review of the laboratory's 2023 American Proficiency Institute (API) immunohematology PT documentation, a total of 3 events (Event 1-3), revealed no signed TP attestation statement for API 2023 Event 2-Blood Bank (ABO/Rh) Module. The inspector noted that the API 2023 Event 2 forms outlined, "Signatures Required- For all PT results, an attestation statement must be signed by testing personnel and retained for minimum of two years." The inspector requested to review a signed attestation for the event

	outlined above. No documentation was available for review. 2. Review of the laboratory procedure manual revealed a Proficiency Testing Policy that stated, "the testing personnel will sign/date the attestation submission to the proficiency program." 3. An exit interview with the lab director on 6/4/24 at 12:00 PM confirmed the above findings