Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0983866	10/11/2018
Name of Provider or Supplier	**Street Address, City, State**	
American Women's Services	6005 Landover Road Suite 6, Cheverly, MD	

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
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 record review and interview with lab staff, the lab did not ensure that proficiency testing records were complete. Findings: 1. The records for the second proficiency test event of 2017 for Rh testing were incomplete, the testing person for the test event was not identified in the test records and at the time of the survey the surveyor could not determine if the proficiency testing reporting form was the intermediate worksheet used by the testing person to document the Rh test results reported to the provider; and 2. This was confirmed with lab staff during interview on the day of survey.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for

	specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory (lab) staff, the lab procedures did not include evaluation and corrective action instructions for Rh quality control results that do not meet the labs criteria for acceptability. Findings: 1. The weekly written procedure for evaluating the Rh positive and Rh negative control reagents (venous whole blood collected from donors with known Rh blood types) did not instruct staff to identify the severity of hemolysis (if present) in the Rh positive and Rh negative controls, and also provide for corrective actions based on the severity of hemolysis; 2. The written procedures did not have photos demonstrating the different degrees of hemolysis; 3. On the day of survey, the two quality control reagents for the Rh test (positive and negative) had not been disturbed for at least one day and the controls both appeared to be hemolyzed as there was no straw colored plasma sitting on the red cells that should have settled as the whole blood sat in the tubes; 4. There was no written instruction for staff to take action based on the degree of hemolysis observed in the control samples; 5. There was no written instruction to evaluate the acceptability of the control reagents based on the differences between the samples original hematocrit and subsequent hematocrits, as a significant drop would indicate deterioration; 6. This was confirmed during interview with lab staff on the day of survey.