Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0983867	07/31/2018
Name of Provider or Supplier	**Street Address, City, State**	
American Women 's Services	3506 North Calvert St, Baltimore, 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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation of laboratory (lab) procedures and interview with lab staff, the lab did not maintain safety data sheets for the anti-D reagent and cleaning solutions that are used in the lab. This was confirmed during interview with lab staff at 10:00 am on the day of survey.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on record review and interview with lab staff, the lab did not manually enter the Rh test results into each of the patient charts on June 21, 2018, when the tests were performed. Findings: 1. On June 21, 2018, one of fifty-eight days of testing reviewed

	for all of 2018 and 2017, the testing person did not enter the patient Rh test results into the patient charts. Three patients had Rh testing performed on this day and the results of the Rh tests were not entered in their charts; and 2. This was confirmed during interview with lab staff at 11:00 am on the day of survey.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: A. Based on record review and interview with laboratory (lab) staff, the laboratory director did not ensure that quality control programs are maintained. Findings: 1. The laboratory written procedure states (see page 8 of 37 in the procedure manual) that staff must check the positive and negative Rh control reagents for hemolysis and deterioration by centrifuging a sample of each control, using the microhematocrit centrifuge, and observing the hematocrit of the controls and the color and clearness of the plasma layer of each control; 2. This check is performed because the control samples are prepared from donors that are collected by the lab, and this check is made to ensure that the samples are not deteriorated since they are used to check the positive and negative reactivity of the anti-D test reagent; and 3. During interview with lab staff on the day of survey (at 10:00 am), staff stated that the microhematocrit centrifuge is not working and that the hematocrit is currently not checked for the control samples, but the color and turbidity of the plasma is checked by observing the plasma after the samples sit overnight in the lab refrigerator. B. Based on record review and interview with lab staff, the lab did not perform quality control checks on the Anti-D reagent (antisera) to check the antisera for positive and negative reactivity. Findings: 1. On June 21, 2018, one of fifty-eight days of testing reviewed for all of 2018 and 2017, the testing person did not perform and report the results of the Rh quality control checks to ensure the reactivity of the antiserum; 2. On June 21, 2018 three patient Rh tests were performed; 2. This was confirmed during interview with lab staff at 11:00 am on the day of survey.