Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D0252327	10/17/2018
Name of Provider or Supplier	**Street Address, City, State**	
Greenville Womens Clinic Pa	1142 Grove Road, Greenville, SC	

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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: During an onsite recertification survey on 10/17/2018, based on immunohematology quality control (QC) record review and testing personnel interview, it was determined that the laboratory failed to ensure that immunohematology control material was not used beyond the printed expiration date for 2 out of 31 days reviewed in December 2016. Findings include: 1. Record review on 10/17/2018 at 12:30pm revealed that the following immunohematology QC lot number was used beyond the printed expiration date: a. Lot number 14281 (positive control) with an expiration date of 12/28/2016: used 12/29/2016 through 12/30/2016 b. Lot number 14282 (negative control) with an expiration date of 12/28/2016: used 12/29/2016 through 12/30/2016 2. Testing personnel confirmed during the onsite exit interview on 10/17/2018 at 1:30 pm that the controls were used past the stated expiration date.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: During an onsite recertification survey on 10/17/2018, based on the laboratory

	procedure manual, lack of documentation and testing personnel interview, the laboratory failed to ensure that testing personnel were evaluated annually after the first year of testing patient specimens for 7 of 7 testing personnel (employees number 1 through 4 and 6 through 8 on the CMS 209) . Findings include: 1. The laboratory listed 7 testing personnel on the CMS-209 on the day of the survey. 2. Documentation of an annual training and evaluation for the years 2016 and 2017 was unavailable for review on the day of the survey for employees number 1 through 4 and 6 through 8 on the CMS 209. 3. Testing personnel confirmed during an onsite interview on 10/17/18 at 1:30pm that the laboratory had failed to ensure that testing personnel were evaluated at least annually after the first year of testing patient specimens.