Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D0252327	05/07/2025
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
D0000	An onsite announced CLIA recertification survey was conducted on May 7, 2025, at the laboratory of the Greenville Women's Clinic by the South Carolina Department of Public Health's (SC DPH) Bureau of Nursing Homes and Medical Services. The laboratory was found to be out of compliance with Medicare condition 42 CFR Part 493, CLIA Requirements for Laboratories. The following is a list of Standard level deficiencies cited:
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (b)(7) 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 records review, lack of documentation, and staff interview, the laboratory failed to maintain copies of attestation statements signed by the laboratory director (LD) and testing personnel (TP) documenting that Proficiency Testing (PT) samples were tested in the same manner as patient samples for 10 out of 10 testing events for 41 out of 41 months reviewed. Findings included: 1. Review of the laboratory's PT policy and procedure reveals the statement: "Testing should be performed as closely as practical as analysis of regular patient sample". 2. Review of the laboratory's PT policy and procedure reveals a lack of documentation of attestation statement's use. 3. In an interview on May 7, 2025, at 12:30pm in the laboratory with Testing Personnel 1 (TP), the findings were confirmed.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable,

	consultant competency. This STANDARD is not met as evidenced by: Based on records review, lack of documentation, and staff interview, the laboratory failed to follow its own written policy and procedure to assess employee competency for 8 out of 8 testing personnel (TP) for 41 out of 41 months reviewed. Findings Included: 1. Review of the "Evaluation" policy and procedure indicates evaluation of employee competency should occur at 6 months in the first year of employment, and annually thereafter. No initial competency was required. 2. Review of personnel records for the staff listed on the CMS 209 form reveals a lack of employee competency documentation. 3. In an interview on May 7, 2025, at 12:30pm in the laboratory with TP1, the findings were confirmed.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on records review, lack of documentation, and staff interview, the laboratory failed to document the ongoing mechanism to monitor, assess, and correct problems using the "Quality Assurance Plan" found in the policy and procedure manual. Findings included: 1. Review of the laboratory's policy and procedure manual reveals a written policy and procedure for the laboratory's quality assurance plan. 2. Review of laboratory records reveals a lack of documentation of quality assurance monitors or activities. 3. In an interview on May 7, 2025, at 1:00pm in the laboratory with TP1, the findings were confirmed.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on records review, lack of documentation, and staff interview, the laboratory failed to document the Laboratory Director's (LD) review and approval of 35 out of 39 procedures reviewed. Findings included: 1. Review of the laboratory policy and procedure manual reveals a lack of documentation that the LD reviewed or approved procedures in use. 2. Review of the CMS 209 laboratory personnel report reveals one laboratory director. 3. In an interview on May 7, 2025, at 12:00pm in the laboratory with TP1, the findings were confirmed.