Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D2065056	10/22/2025
Name of Provider or Supplier	**Street Address, City, State**	
Pee Dee Pathology-Myrtle Beach	915 Medical Circle, Myrtle Beach, 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 recertification survey was conducted at PEE DEE PATHOLOGY on October 22, 2025. The facility was found to be out of compliance with the Medicare Condition at 42 CFR Part 493. CLIA Laboratory Requirements. The following is a list of STANDARD Level deficiencies cited as a result of the CLIA recertification survey on October 22, 2025.
D5207	COMMUNICATIONS CFR(s): 493.1234 The laboratory must have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results. This STANDARD is not met as evidenced by: Based on records review, lack of documentation, and staff interview, the laboratory failed to document corrective actions taken to resolve problems with policies and procedures necessary to prevent recurrence of problems, and documented discussions of general laboratory systems quality assessment reviews with testing personnel. Findings included: 1. Review of quality assurance policy and data reveals the laboratory's lack of documentation for meeting minutes and/or recordings of discussions with laboratory director, testing personnel, and quality manager. 2. Review of antibody validations reveals a lack of documentation of laboratory director's review and approval. 3. Review of Histopathology Quality Control/Quality Assessment reveals a lack of documentation of laboratory director's review, signature and date. 4. In an interview with testing personnel on October 22, 2025, at 3:11 pm in the office the above findings were confirmed.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)

	(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on records review, lack of documentation, and staff interview, the laboratory failed to document revision of policies and procedures and discussion of general laboratory systems quality assessment reviews with appropriate staff. Findings included: 1. Review of CMS 116 application and CMS 209 reveal one laboratory director. 2. Review of policies and procedures reveal lacks documentation of laboratory director's review. 3. Surveyor requested but laboratory failed to provide laboratory director's signature and date of policies and procedures reviewed. 4. In an interview with testing personnel on October 22, 2025, at 3:11 pm in the office the above findings were confirmed.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on records review, lack of documentation, and staff interview, the laboratory failed to establish and verify performance specifications for equipment before reporting patient test results as required 493.1253. Findings included: 1. Review of CMS 116 application and CMS 209 reveals a different address from previous survey. 2. Surveyor requested but the laboratory failed to provide a verification of performance on the equipment that was moved to the new office before patient's results were reported. 3. The surveyor toured the laboratory and directly observed the following equipment in use in the laboratory: a. Tissue Tek VIP b. Sakura Prs 2000 c. Thermo Scientific Microm HM 520 d. Ventana Benchmark Ultra e. Olympus BX40 in the lab f. Olympus BX45 in the Pathologist office g. Air Clean 600, Hood 4. In an interview with testing personnel on October 22, 2025, at 3:11 pm in the office the above findings were confirmed.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on records review, lack of documentation, and staff interview, the laboratory

	director failed to establish adequate verification procedures to determine the accuracy, precision, and other pertinent performance characteristics of the method for 7 of 7 pieces of equipment. Reference D5421
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) (e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on records review, lack of documentation and testing personnel interview, the laboratory director failed to ensure that an established and approved procedure manual was available to testing personnel for 5 out 5 months reviewed (May 1, 2025, through October 22, 2025) (see D5293).