

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D2270341	(X3) Date Survey Completed 11/18/2024
Name of Provider or Supplier Pee Dee Pathology Associates	Street Address, City, State 3420 Overcreek Road, Columbia, 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 initial survey was conducted at Pee Dee Pathology Associates-Columbia on November 18, 2024, by South Carolina Department of Public Health's (SCDPH), Bureau of Nursing Homes and Medical Services. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. The facility was found to be out of compliance with the standards of the CLIA program. The following STANDARD LEVEL DEFICIENCIES were found to be out of compliance:
D5601	<p>HISTOPATHOLOGY CFR(s): 493.1273(a)(f)</p> <p>(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on record review and laboratory director (LD) interview, the laboratory failed to record the reaction(s) of the control slide with each special stain. The laboratory must document all control procedures performed, as specified in 493.1256(e)(3). Findings include: 1) During an onsite initial survey, the surveyor reviewed policies and procedures and patient reports on 11/18/2024 revealed the following: a. The policy titled "Quality Management Program" under special stains/and immunohistochemistry, states "All positive and negative controls (IHC) should be reviewed by the technologist before release." b. The policy does not state the need to document the reaction of any controls. 2) Review of patient reports case number: SBM24-0017 IC, reveal signatures of Histotech and pathologist signifying all positive</p>

and negative controls have been reviewed. No reaction of stain is recorded on patient report or on quality control log. 3) In an interview with the LD on 11/08/2024 at 12:42 pm the above findings were confirmed.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on record review and LD interview, the laboratory failed to record the name and address of the laboratory location where the test was performed. Findings include:
1. The surveyor directly observed a patient's final report on 11/08/2024 reveal the name Pee Dee Pathology and location as "Carolina Facial Plastic Surgery" Case Number: S2024-016475. The report was electronically signed by LD on 11/18/2024 at 1304 at his home office. The final report lacked the address of where the test was performed. 2. In an interview with the LD on 11/18/2024 at 13:05 the above findings were confirmed.