Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D2089748	01/07/2026
Name of Provider or Supplier	**Street Address, City, State**	
Muscp-Pc Northwoods Lab	2154 N Center Street A105, North Charleston, 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 announced CLIA onsite recertification survey was conducted at MUSC-PC Northwoods Lab on January 07, 2026, by South Carolina Department of Public Health (SC DPH), Bureau of Nursing Homes and Medical Services. The facility was found to be out of compliance with the Medicare Condition at 42 CFR Part 493. CLIA laboratory requirements. The following STANDARD LEVEL DEFICINCIES were found to be out of compliance:
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 record review, lack of documentation, and staff interviews, the laboratory failed to document ongoing review of all facets of the laboratory's monitoring of corrective actions to ensure action(s) taken have prevented recurrence of the original problem. The correction process involves investigation, identification, and resolution of the problem, followed by development of policies that will prevent recurrence. 1. A record review of patient results from the Hematology Method Comparison revealed low and/or out of range results. 2. The surveyor requested and the laboratory failed to provide documentation of an investigation and/or resolution of the patients out of range test results. 3. In an interview on January 7, 2026, at 4:00 pm in the office with the laboratory technical consultants [(TC) TC1 & TC 2] the above findings were confirmed.
D5777	COMPARISON OF TEST RESULTS CFR(s): 493.1281(b)(c)

	(b) The laboratory must have a system to identify and assess patient test results that appear inconsistent with the following relevant criteria, when available: (b)(1) Patient age. (b)(2) Sex. (b)(3) Diagnosis or pertinent clinical data. (b)(4) Distribution of patient test results. (b)(5) Relationship with other test parameters. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and staff interviews, the laboratory failed to document test result comparison for personnel performing manual white blood cell (WBC) differentials. The laboratory failed to have procedures to assess testing personnel manual differential test counts to evaluate any inconsistencies in patient results. 1. A review of patient test results reveals personnel performing WBC differential counts. 2. The surveyor requested and the laboratory failed to provide documentation of personnel assessment and evaluation of any manual count inconsistencies between testing personnel. 3. In an interview on January 7, 2026, at 4: 00 pm in the office with the laboratory TC1 & TC 2 the above findings were confirmed.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and staff interviews, the laboratory failed to document the laboratory's corrective action to include sufficient information to resolve the problem and prevent recurrence. 1. A record review of "Weekly Huddle for January 6, 2025" involving patient results out of range and critically low lack documentation of who the issues were communicated with, what approved process was put in place to prevent reoccurrence. 2. The surveyor requested and the laboratory failed to provide documentation of periodic review of quality monitoring and assessment with laboratory director, technical consultants, and staff. 3. In an interview on January 7, 2026, at 4:00 pm in the office with the laboratory TC1 & TC 2, the above findings were confirmed.