Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D1106377	01/21/2026
Name of Provider or Supplier	**Street Address, City, State**	
Musc Health Chester Medical Center Dba	148 Sauls Street, Suite C, Lake City, 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 the MUSC Health Chester Medical Center Laboratory on January 21, 2026, by the 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 Medicare Condition 42 CFR Part 493. CLIA laboratory requirements. The following STANDARD LEVEL DEFICINCIES were found to be out of compliance:
D2014	TESTING OF PROFICIENCY TESTING SAMPLES (b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and staff interview, the laboratory failed to ensure that the analyst performing the proficiency testing (PT) signed the statement attesting that PT samples were tested in the same manner as patient specimens for 1 of 2 years reviewed (2024 and 2025). Findings included: 1. Review of American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) PT records reveal attestation page for the following events: a.AAB-MLE M1 2025, Potassium hydroxide (KOH) Slides, performed 02/11/2025 b.AAB-MLE M2 2025, KOH Slides, performed 05/20/2025 c.AAB-MLE M3 2025, KOH Slides, performed 09/22/2025 2. A review of the attestation pages for AAB-MLE 2025 reveals 3 out of 3

	events lack documentation of testing personnel's signature(s). 3. In an interview on January 21, 2026, at 5:30 pm in the conference room with office manager and testing personnel the above findings were confirmed.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on policy and procedures review, lack of documentation, and staff interview, the laboratory failed to document when a procedure was modified and verified /established as specified. Procedure manual changes lack documentation of when changes were communicated to laboratory personnel for the 3 years reviewed (2023, 2024, and 2025). Findings included: 1. A review of procedure manual policy titled "MUSC Health Florence Medical Center" state "Each procedure is signed and dated by the lab director and thereafter initialed and dated at the time of annual review." 2. A review of policy and procedure manual reveals many updates, changes and amendments were made and signed by the laboratory director(s). All policies and procedures lack the date the changes and/or signature(s) were made. 3. In an interview on January 21, 2026, at 5:30 pm in the conference room with office manager and testing personnel the above findings were confirmed.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and staff interviews, the laboratory failed to update and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified. The laboratory failed to have performance indicators measuring the quality of their services and lack documentation of any assessment and/or communication regarding analytic systems. Findings included: 1. Review of Policy and Procedure: Laboratory Manual, Subject: Quality Assurance, General reveal "Remedial action should include the date, the problem, what course of action was taken to resolve the problem, whether or not the problem was resolved, and who worked on the problem." 2. A review of staff meetings, corrective actions for PT failures, quality controls ran after instrument installation reveal lack of documentation for assessment and/or resolution of problems identified, lack policy and procedures that will prevent recurrence. 3. In an interview on January 21, 2026, at 5:30 pm in the office with the office manager and testing personnel, the above findings were confirmed.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13)

	(e)(13) 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 policy and procedure review, lack of documentation, and staff interview, the laboratory director failed to date and approve new and revised procedures. The laboratory documented the purchase of a new Clinitek Status instrument for April of 2025. Procedures lack documentation of LD approval date for new and revised procedures. Findings included: 1. Review of unacceptable PT results by laboratory director (LD) on April 2, 2025, revealed approval for a new urinalysis instrument. 2. Review of policy and procedure for Urinalysis/Clinitek Status Analyzer lack documentation of the date and approval of the new and/or revised procedure. 3. Review of the policy and procedures document revisions but lack the date testing personnel signed and/or was informed. 4. In an interview on January 21, 2026, at 5:30 pm in the conference room with office manager and testing personnel the above findings were confirmed.