Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D1047824	05/18/2026
Name of Provider or Supplier	**Street Address, City, State**	
Charleston Center-Dept Of Alcohol & Dr	3685 Rivers Avenue, Suite 301, 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 onsite announced recertification survey was conducted at Charleston Center on May 18, 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 the Medicare Conditions 42 CFR Part 493, CLIA laboratory requirements. The following STANDARD LEVEL DEFICINCIES were found to be out of compliance as a result of the recertification survey on May 18, 2026:
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 record review, lack of documentation, and staff interview, the laboratory failed to establish and/or follow written policies to assess employees for 3 out of 3 years reviewed (20023, 2024, and 2025). Findings included: 1. Review of CMS 209 Personnel Report record reveals 2 testing personnel. a. TP1 b. TP2 2. The surveyor requested and the laboratory failed to provide a written policy on personnel competency assessment. 3. In an interview on May 18, 2026, at 4:52 pm in the conference room with office manager and TP1 the above findings were confirmed.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

	This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to verify the accuracy of the tests twice annually as required 493.1236 for 3 out of 3 years reviewed (2023, 2024, and 2025). Findings included: 1. A review of American Proficiency Institute (API) records reveals the following results: a. 2023 Chemistry-Miscellaneous-1st Event, Urine Drug Screen (UDS) Amphetamines qualitative (qual), received unsatisfactory score of 33%. a. 2023 Chemistry-Miscellaneous-1st Event, Urine Drug Screen (UDS) Amphetamines qualitative (qual), received unsatisfactory score of 33% b. 2023 Chemistry- Miscellaneous-1st Event, UDS Buprenorphine (qual), received unsatisfactory score of 33%. c. 2023 Chemistry- Miscellaneous-2nd Event, UDS Ethyl Glucuronide, received unsatisfactory score of 0%. d. 2023 Chemistry- Miscellaneous-2nd Event, UDS Amphetamines (qual), received unsatisfactory score of 0%. e. 2023 Chemistry- Miscellaneous-2nd Event, UDS Benzodiazepines (qual), received unsatisfactory score of 0%. f. 2023 Chemistry-Miscellaneous-2nd Event, UDS Cannabinoids (qual), received unsatisfactory score of 0%. g. 2023 Chemistry- Miscellaneous-2nd Event, UDS Cocaine Metabolites (qual), received unsatisfactory score of 0%. h. 2023 Chemistry- Miscellaneous-2nd Event, UDS Methadone (qual), received unsatisfactory score of 0%. i. 2023 Chemistry-Miscellaneous-2nd Event, UDS Opiates (qual) , received unsatisfactory score of 0%. j. 2023 Chemistry- Miscellaneous-2nd Event, UDS Oxycodone (qual), received unsatisfactory score of 0%. k. 2024 Chemistry- Miscellaneous-1st Event, UDS Cocaine Metabolites (qual), received unsatisfactory score of 67%. l. 2024 Chemistry-Miscellaneous-2nd Event, Ethyl Glucuronide, received unsatisfactory score of 67%. m. 2025 Chemistry- Miscellaneous-2nd Event, Ethyl Glucuronide, received unsatisfactory score of 67%. 2. In an interview on May 18, 2026, at 4:52 pm in the conference room with office manager and TP1 the above 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 policies and procedures review, lack of documentation, and staff interview, the laboratory failed to 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. Findings included: 1. Review of policy titled "UDS Quality Assurance Program" reveals the laboratory Quality Assurance Program would identify, correct, and communicate problems to assure the accurate, reporting of test results. The results of all QA findings will be discussed with the laboratory staff, and a copy of the QA program findings will be kept in the Quality Assurance Binder. 2. The surveyor requested and the laboratory failed to provide documentation of QA findings with laboratory director and staff for 3 out of 3 years reviewed (2023, 2024, and 2025). 3. In an interview on May 18, 2026, at 4:52 pm in the conference room with office manager and TP1 the above 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 policies and procedures reviewed, lack of documentation, and staff interview, the laboratory director failed to approve procedure changes by signing and dating the change for the 3 out of 3 years reviewed (2023, 2024, and 2025). Findings included: 1. A review of "UDS Quality Assurance Program" policy reveals Effective Date 12-05, Policy Number 6.1, Page Number 2 of 2, a change was made. The test menu was updated to add Barbiturates (BARBS) and Ecstasy (MDMA). 2. The policy lacked documentation about when the procedure was updated/approved and what date it was communicated to staff. 3. In an interview on May 18, 2026, at 4:52 pm in the conference room with office manager and TP1 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 record review, lack of documentation, and staff interview, the laboratory director failed to ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process for 3 of 3 years reviewed (2024, 2025, and 2026). Findings included: 1. Review of policies and procedures reveals the laboratory lack written procedure for tests performed on the new Beckman AU 480 analyzer installed April 2025. 2. Review of policies and procedures reveals the laboratory lack documentation of director's approval for the Beckman AU 480 analyzer installed April 2025. 3. In an interview on May 18, 2026, at 4:52 pm in the conference room with office manager and TP1 the above findings were confirmed.
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and staff interview, the Technical Consultant failed to document the training and education provided to testing personnel (TP) for moderately complex testing performed for the 3 out of 3 years reviewed (2024, 2025, and 2026). Findings included: 1. Records reviewed (CMS 209 Personnel Report form and API Attestation Statements) reveal 2 TPs. a. TP1 b. TP2 c. TP2, 2024 Chemistry-Miscellaneous-2nd Event signed attestation statement October 25, 2024 2. The surveyor requested and the laboratory failed to provide training records

	for 1 out of 2 TP hired in 2024. a. TP2 3. In an interview on May 18, 2026, at 4:52 pm in the conference room with office manager and TP1 the above findings were confirmed.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to-- This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and staff interview, the Technical Consultant failed to document and include all 6 competency assessment procedures for 2 out of 2 TP performing patient testing as required 493.1413(b)(8) for 3 out of 3 years reviewed (2024, 2025, and 2026). Findings included: 1. Review of CMS 209 Personnel Report Form and PT attestation sheets reveal 2 TP. a. TP1 b. TP2 2. The surveyor requested competency evaluations for both TPs and the laboratory lack documentation for 3 out of 3 years for 2 out of 2 TPs performing moderately complex testing. 3. In an interview on May 18, 2026, at 4:52 pm in the conference room with office manager and TP1 the above findings were confirmed.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and staff interview, the TC/laboratory director failed to evaluate and/or document the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tested patient specimens for 1 out of 2 testing personnel (TP). Findings included: 1. Review of CMS 209 Personnel Report Form and PT attestation records reveal 2 TP. a. TP1 b. 2TP2 c. TP2, 2024 Chemistry-Misellaneous-2nd Event signed attestation statement October 25, 2024 d. TP2, 2025 Chemistry-Misellaneous-1st Event signed attestation statement May 7, 2025. 2. The surveyor requested and the laboratory failed to provide semiannually competency for TP2 hired 2024. 3. In an interview on May 18, 2026, at 4:52 pm in the conference room with office manager and TP1 the above findings were confirmed.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and staff interview, the TC/laboratory

	director failed to evaluate and/or document the performance of individuals responsible for moderate complexity testing at least annually for individuals testing patient specimens for 2 out of 2 testing personnel (TP). Findings included: 1. Review of CMS 209 Personnel Report record reveals 2 testing personnel. a. TP1 b. TP2 2. The surveyor requested and the laboratory failed to provide annual competency for 2 out of 2 TP. 3. In an interview on May 18, 2026, at 4:52 pm in the conference room with office manager and TP1 the above findings were confirmed.