

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  42D1047824	<b>(X3) Date Survey Completed</b>  09/22/2023
<b>Name of Provider or Supplier</b>  Charleston Center-Dept Of Alcohol & Dr	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Recertification Survey was initiated on 09/22/2023 and concluded on 09/22/2023. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
<b>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory failed to ensure a laboratory director and testing personnel signed a proficiency testing attestation statement for 1 of 3 proficiency test events reviewed. Findings included: A review of a "2023 Chemistry Miscellaneous 1st Event Attestation Statement" indicated, "An attestation statement must be signed by testing personnel and the laboratory director and retained for a minimum of 2 years." The review revealed that the statement was not signed by the laboratory director or the person(s) who performed the test. During an interview on 09/22/2023 at 11:40 AM, Testing Personnel (TP) #2 stated that they usually did not complete the attestation forms for proficiency testing. The attestation statement forms for 2022, events 1 and 2, were not available for review.</p>
<b>D6046</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (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.</p>

This STANDARD is not met as evidenced by:

Based on observation, interviews, and document review, the laboratory failed to ensure that an initial competency assessment was documented for 1 (Testing Personnel [TP] #1) of 2 testing personnel reviewed. Findings included: During the laboratory tour on 09/22/2023 at 10:00 AM, TP #1 was observed loading samples on a urine drug screen analyzer. During an interview at 10:00 AM, TP #1 provided an overview of specimen collection, preparation, and testing on the analyzer. A review of TP #1's personnel file revealed TP #1 started working in the laboratory on 10/07/2022. In response to a request for evidence showing TP #1 received initial training on using the analyzer, the facility provided TP #1's completion certificates from the manufacturer's online modules. During an interview on 09/22/2023 at 11:05 AM, TP #2 stated they observed TP #1 perform laboratory testing and tasks after completion of each online module, but the performance was not documented.