

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D2052202	(X3) Date Survey Completed 08/27/2025
Name of Provider or Supplier Southern Urgent Care	Street Address, City, State 3583 Hwy 17 Bypass, Murrells Inlet, 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 CLIA recertification survey was performed on August 27, 2025, at the laboratory of Southern Urgent Care of Murrells Inlet by the South Carolina Department of Public Health (SC DPH) Bureau of Nursing Homes and Medical Services. The laboratory was found to be out of compliance with Medicare condition 42 CFR Part 493. CLIA requirements for laboratories. Below is a list of Condition and Standard level deficiencies cited as a result of the August 27, 2025 recertification survey. D2000 493.801 Enrollment and Testing of Proficiency Testing (PT) samples D2016 493.803 Successful participation in PT program D6000 493.403 Laboratory director provides overall management and direction of the laboratory
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on records review and staff interview, the laboratory failed to enroll in a HHS approved proficiency testing (PT) program. Findings included: 1. Review of laboratory policies and procedures reveals a written procedure for "Proficiency Testing Assessment" 2. Surveyor requested documentation of enrollment in a PT program, but no documentation was provided by the laboratory. 3. In an interview on August 27, 2025 at 1:00pm with the Technical Consultant (TC) in the laboratory, the findings were confirmed.</p>

D2016

SUCCESSFUL PARTICIPATION

CFR(s): 493.803(a)(b)(c)

(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.

This CONDITION is not met as evidenced by:

Based on records review and staff interview, the laboratory failed the successfully participate in a HHS approved PT program. Findings included: 1. Review of laboratory policies and procedures reveals a written procedure for "Proficiency Testing Assessment" 2. Surveyor requested documentation of enrollment in a PT program, but no documentation was provided by the laboratory. 3. In an interview on August 27, 2025 at 1:00pm with the Technical Consultant (TC) in the laboratory, the findings were confirmed.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR

CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on records review and staff interview, the laboratory director failed to provide overall management and direction of the laboratory. Findings included: 1. Review of laboratory policies and procedures reveals a written procedure for "Proficiency Testing Assessment" reviewed and approved by the LD. 2. Surveyor requested documentation of enrollment in a PT program, but no documentation was provided by the laboratory. 3. In an interview on August 27, 2025 at 1:00pm with the Technical Consultant (TC) in the laboratory, the findings were confirmed.

D6015

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)

(e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that--

This STANDARD is not met as evidenced by:
Based on records review and staff interview, the laboratory director failed to ensure that the laboratory was enrolled in a HHS approved PT program. Findings included: 1. Review of laboratory policies and procedures reveals a written procedure for "Proficiency Testing Assessment" 2. Surveyor requested documentation of enrollment in a PT program, but no documentation was provided by the laboratory. 3. In an interview on August 27, 2025 at 1:00pm with the Technical Consultant (TC) in the laboratory, the findings were confirmed.