

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D2141062	(X3) Date Survey Completed 10/03/2024
Name of Provider or Supplier Southern Med Pediatrics Fort Mill	Street Address, City, State 342 Patricia Ln, Suite 105, Fort Mill, 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	The following deficiencies are the result of a desk review of proficiency testing (PT) scores performed by the South Carolina Department of Public Health on 10/03/2024. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. PT scores obtained from the national database and verified with the proficiency testing company. The facility was found to be out of compliance with the CONDITIONS and STANDARDS of the CLIA program. The following CONDITION(S) and STANDRD (S) LEVEL DEFICIENCIES were found to be out of compliance: D2016-42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D2123-42 C.F.R. 493.851 Standard: Hematology D2130-42 C.F.R. 493.851 Standard; Hematology
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p>

This CONDITION is not met as evidenced by:
Based on the review of the Casper report 0155D and proficiency testing reports from the Wisconsin State Laboratory of Hygiene (WSLH) for Hematology events 1 and 2, the laboratory failed to successfully participate in a proficiency testing (PT) program approved by CMS. Findings included: 1. Review of Casper Report 0155D for events 2024-HemeReg1 and 2024 HemeReg 2 reveals scores of 0%. 2. Review of the WSLH-2024 HemeReg1 and WSLH-2024 HemeReg2 reveals that the laboratory failed to submit results for both events. 3. Failure to successfully participate in 2 out of 3, or 2 consecutive PT events constitutes a Condition Level Deficiency.

D2123

HEMATOLOGY
CFR(s): 493.851(c)

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:
Based on the review of the Casper Report 0155D and WSLH PT scores, the laboratory failed to participate in a testing event and resulting in unsatisfactory performance with a score 0% for the 2024 Hematology events 1 and 2. Findings included: 1. Review of Casper Report 0155D for events 2024-HemeReg1 and 2024 HemeReg 2 reveals scores of 0%. 2. Review of the WSLH-2024 HemeReg1 and WSLH-2024 HemeReg2 reveals that the laboratory failed to submit results for both events. 3. Failure to participate in a testing event is unsatisfactory performance and results in a score 0% for the testing event.

D2130

HEMATOLOGY
CFR(s): 493.851(f)

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Based on review of the Casper Report 0155D and 2024 WSLH PT scores reveals failure to achieve satisfactory performance in two consecutive Hematology events. Findings included: 1. Review of Casper Report 0155D for events 2024-HemeReg1 and 2024 HemeReg 2 reveals scores of 0%. 2. Review of the WSLH-2024 HemeReg1 and WSLH-2024 HemeReg2 reveals that the laboratory failed to submit results for both events. 3. Failure to participate in a testing event is unsatisfactory performance and results in a score 0% for the testing event.