

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0958035	(X3) Date Survey Completed 08/28/2023
Name of Provider or Supplier Community Physicians/Sager Pediatric	Street Address, City, State 1101-2 North Progress Ave, Siloam Springs, AR	
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	A desk review of proficiency testing was performed on October 28, 2023. The laboratory was found to be not in compliance with the following conditions: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director
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> <p>This CONDITION is not met as evidenced by: Based on review of the 2022 and 2023 CMS Casper Reports 096D, 0153D, and the American Proficiency Institute (API) proficiency testing results, the laboratory failed to have successfully participate in proficiency testing in the specialty of Hematology</p>

	<p>for the analyte White Blood Cell Differential (WBC DIFF). Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance as cited at D2130.</p>
D2130	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2022 and 2023 CMS Casper Reports 096D, 0153D, and the American Proficiency Institute (API) proficiency testing results, the laboratory failed to achieve satisfactory performance for the analyte WBC DIFF in three of four testing events. A. A review of the proficiency testing results revealed the laboratory received a score of 0% for the test of WBC DIFF in the second proficiency testing event of 2022. B. A review of the proficiency testing results revealed the laboratory received a score of 0% for the test of WBC DIFF in the third proficiency testing event of 2022. C. A review of the proficiency testing results revealed the laboratory received a score of 0% for the test of WBC DIFF in the second proficiency testing event of 2023.</p>
D6000	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of 2022 and 2023 proficiency testing events, laboratory director failed to ensure the overall management and direction of laboratory services. Refer to D6016.</p>
D6016	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;</p> <p>This STANDARD is not met as evidenced by: Based on review of the 2022 and 2023 proficiency testing events, the laboratory director failed to ensure successful participation in a proficiency testing program for the Hematology test of WBC DIFF. Refer to D2130.</p>