

| | | |
|--|---|---|
| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 04D0958035 | (X3) Date Survey Completed 01/12/2023 |
| 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 |
|---------------------------|---|
| 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 2022 CMS Casper Reports 155D, 153D and American Proficiency Institute (API) proficiency testing results, it was determined the laboratory failed to have successful participation in proficiency testing for the test of White Blood Cell Differential (WBC DIFF) as evidenced by: Failure to achieve satisfactory performance for test of WBC DIFF in two out of three proficiency testing events is unsuccessful performance, as cited at D2130.</p> |
| D2130 | <p>HEMATOLOGY CFR(s): 493.851(f)</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.

This STANDARD is not met as evidenced by:

. Based on review of the 2022 CMS Casper Reports 155D and 153D and API proficiency testing results, it was determined the laboratory failed to successfully participate in the second proficiency testing event of 2022 and the third proficiency testing events of 2022, resulting in a score of 0% for the test of White Blood Cell Differential (WBC DIFF), as evidenced by: A. A review of proficiency test scores for 2022 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 proficiency test scores for 2022 revealed the laboratory received a score of 0% for the test of WBC DIFF, in the third proficiency testing events of 2022.

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 review of 2022 proficiency testing scores, it was determined the laboratory director failed to provide overall management and direction as evidence by: A. Failure to achieve satisfactory performance for the analyte of WBC DIFF in two consecutive testing events, as cited at D2130.

D6019

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iv)

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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

. Based on review of 2020 and 2021 CMS Casper Reports 155D, 153D and American Association of Bioanalysts proficiency testing results, it was determined the Laboratory Director failed to ensure that corrective action is followed when proficiency testing results are unacceptable as cited at D 2016 and D2130.