

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0384646	(X3) Date Survey Completed 05/02/2024
Name of Provider or Supplier Buchanan County Health Center	Street Address, City, State 1600 First Street East, Independence, IA	
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 proficiency testing desk review survey was completed on May 2, 2024, the laboratory was found to be out of compliance with the following CONDITION LEVEL DEFICIENCIES: D2016 - 42 C.F.R 493.803 Condition: Successful Participation D6000 - 42 C.F.R 493.1043 Condition: Laboratory Director, moderate complexity
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 Certification and Survey Provider Enhanced Reporting (CASPER) 155 report and graded results from the American Proficiency Institute (API) and WSLH Proficiency Testing (WSLH), the laboratory failed to successfully</p>

	<p>participate in three out of four consecutive testing events in the specialty of Hematology for the analyte, white blood cell differential (WBC DIFF). The laboratory had unsatisfactory scores for 2023 events 1 and 3 and 2024 event 1. Refer to D2130.</p>
<p>D2130</p>	<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 the Certification and Survey Provider Enhanced Reporting (CASPER) 155 report and graded results from the American Proficiency Institute (API) and WSLH Proficiency Testing (WSLH), the laboratory failed to achieve satisfactory performance (80% or greater) for three out of four consecutive testing events in the specialty of Hematology for the analyte, WBC DIFF. The findings include: 1. For 2023 event 1, the laboratory received an unsatisfactory performance score of 40% for the analyte, white blood cell differential. 2. For 2023 event 3, the laboratory received an unsatisfactory performance score of 68% for the analyte, white blood cell differential. 3. For 2024 event 1, the laboratory received an unsatisfactory performance score of 64% for the analyte, white blood cell differential. 4. The CASPER 155 report and graded results from API and WSHL confirm the above findings.</p>
<p>D6000</p>	<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 the Certification and Survey Provider Enhanced Reporting (CASPER) 155 report and graded results from API (2023 events 1 and 3) and WSLH (2024 event 1), the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6016.</p>
<p>D6016</p>	<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 Certification and Survey Provider Enhanced Reporting (CASPER) 155 report and graded results from the American Proficiency Institute</p>

(API) and WSLH Proficiency Testing (WSLH), the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program. Refer to D2130.