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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>43D0407466           | <b>(X3) Date Survey Completed</b><br>09/10/2025 |
| <b>Name of Provider or Supplier</b><br>Sanford Chamberlain   | <b>Street Address, City, State</b><br>300 South Byron Boulevard, Chamberlain, SD |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>   |
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| <b>D2016</b>              | <p><b>SUCCESSFUL PARTICIPATION</b><br/>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:<br/>Based on proficiency testing (PT) record review and interview with the laboratory manager, the laboratory failed to achieve successful participation for the blood cell identification test method. Unsatisfactory results had been received in two of three PT testing events (American Proficiency Institute [API] Hematology/Coagulation 2024 third and 2025 second testing events) resulting in unsuccessful PT participation. Refer to D2130.</p> |
| <b>D2130</b>              | <p><b>HEMATOLOGY</b><br/>CFR(s): 493.851(f)</p>  |

(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 record review and interview, the laboratory failed to achieve satisfactory proficiency testing (PT) performance for the blood cell identification test method in two out of three events (American Proficiency Institute [API] Hematology /Coagulation 2024 third and 2025 second testing events) resulting in unsuccessful performance. Findings include: 1. Review of the laboratory's CASPER Reports 153D and 155D on 9/1/25 revealed the API PT scores for the blood cell identification test method were less than the 80% required to pass an event per Clinical Laboratory Improvement Amendments requirements found at CFR 493.861(a): a. 2024 Hematology/Coagulation second event score had been 60%. \*BCI-11 had been reported as platelet(s), giant. The acceptable identification had been polychromatophilic red blood cell (RBC). \*BCI-14 had been reported as a monocyte. The acceptable identification had been neutrophil, band (stab). b. 2025 Hematology /Coagulation third event score had been 60%. \*BCI-06 had been reported as a spherocyte. The acceptable identification had been polychromatophilic RBC. \*BCI-07 had been reported as a monocyte. The acceptable identification had been metamyelocyte (juvenile). 2. Interview with the laboratory supervisor via email on 9/8 /25 revealed: a. She confirmed the unsuccessful PT performance. b. After the first unsuccessful PT event, she provided the technologist with education concerning the identification of blood cells and instruction on the correct method for PT result submission. c. After the second unsuccessful event the laboratory manager performed a root cause analysis. It was determined the technologists had interpreted the abnormal cell morphology incorrectly. \*The technologists, who had participated in the unsuccessful PT events, completed a focused review of peripheral smear morphology using reference materials, hematology atlases, and internal teaching slides. A discussion of commonly misidentified cells had been included in the retraining. \*Each technologist performed ten manual differentials on random patient specimens and re-identified ten previously validated PT slide/cell images to ensure accuracy of blood cell identification. All results were reviewed by the laboratory manager for acceptability. \*The laboratory manager directly observed the technologists reviewing slides to ensure correct technique and accurate reporting.