

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D0407466	(X3) Date Survey Completed 09/02/2026
Name of Provider or Supplier Sanford Chamberlain	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A recertification survey for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 9/2/26. The Sanford Chamberlain laboratory was found not in compliance.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (b)(7) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to maintain a copy of the required documentation related to the processing of 20 of 21 proficiency testing (PT) events reviewed (2025 Chemistry Core 1st, 2nd and 3rd events; 2025 Hematology/Coagulation 1st, 2nd and 3rd events; 2025 Microbiology 1st, 2nd and 3rd events; 2025 Immunology/Immunohematology 1st, 2nd and 3rd events; 2025 Chemistry Miscellaneous 1st and 2nd events; 2026 Chemistry Core 1st and 2nd events; 2026 Hematology/Coagulation 1st event; 2026 Microbiology 2nd event; 2026 Immunology/Immunohematology 1st event; 2026 Chemistry Miscellaneous 1st event). Findings include: 1. Review of the laboratory's 2025 and 2026 American Proficiency Institute (API) PT event records on 9/2/26 revealed that the laboratory had subscribed to PT events through API. PT specimens were processed, and the results were submitted electronically via the company's website upon completion of testing. The laboratory had the ability to print a copy of the final PT results that were submitted for evaluation. The laboratory did not retain copies of the final electronically submitted results for evaluation for the following events: 2025 Chemistry Core 1st, 2nd, and 3rd events; 2025 Hematology/Coagulation 1st, 2nd, and 3rd events; 2025 Microbiology 1st, 2nd, and 3rd events; 2025 Immunology/Immunohematology 1st, 2nd, and 3rd events; 2025 Chemistry Miscellaneous 1st and 2nd events; 2026 Chemistry Core 1st and 2nd events; 2026 Hematology/Coagulation 1st event; 2026 Microbiology 2nd

	event; 2026 Immunology/Immunohematology 1st event; 2026 Chemistry Miscellaneous 1st event. Review of the laboratory's PT policy, last reviewed on 7/1/25, revealed that a copy of the electronic upload should be printed and filed. Interview on 9/2/26 at 1:45 p.m. with general supervisor A revealed PT results were submitted electronically after they were processed. The laboratory was able to print copies of all final PT results submitted for evaluation. The laboratory did not print copies of the final submitted PT results for the PT events listed above.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to ensure that one of seven laboratory personnel (technical consultant B) had received a competency evaluation in 2024, 2025, and through the date of the survey for the duties they had performed under the laboratory's certificate. Findings include: 1. Review of the employee competency records on 9/2/26 at 10:30 a.m. revealed technical consultant B did not have an annual competency assessment for their duties performed in 2024, 2025, and through the date of the survey. A request was made to general supervisor A for any additional documentation of an annual competency assessment completed for 2024, 2025, and 2026, and no additional documentation was provided. Review of the laboratory's competency assessment policy, last revised on 10/30/24, revealed the Laboratory Director would delegate duties in writing to qualified employees, including technical consultants. The delegated duties would have a performance assessment performed annually. Interview on 9/2/26 at 1:30 p.m. with general supervisor A revealed, technical consultant B did not have a competency assessment documented for 2024, 2025, and through the date of the survey.