Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D0407466	08/06/2024
Name of Provider or Supplier	**Street Address, City, State**	
Sanford Chamberlain	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 8/6/24. Sanford Chamberlain laboratory was found not in compliance with the following requirements: D5221, D6091 and D6127.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to ensure proficiency testing (PT) results had been reviewed, evaluated, and those activities documented for 9 of 24 PT events reviewed (American Proficiency Institute [API] 2023 Hematology /Coagulation first and third event; 2023 Chemistry Core second event; 2023 Microbiology first and second events; 2024 Hematology/Coagulation first event; 2024 Chemistry Core first event; 2024 Chemistry Core Verification Comparative Evaluation first event; and 2024 Microbiology second event). The failure to identify the potential cause of the unacceptable and ungraded results could have led to a failure to identify inaccurate patient test results. Findings include: 1. Review on 8/6/24 of the API 2023 and 2024 PT event evaluations revealed: a. 2023 Hematology/Coagulation first event *Educational Blood Cell Identification DIF (manual differential- count of the various white blood cells present in the specimen) DF-01 (which included the following analytes Basophil %; Eosinophil %; Immature cell %; Lymphocyte %; Lymphocyte, reactive %; Monocyte %, Neutrophil, band %; Neutrophil, segmented or band %; Neutrophil, segmented %, NRBC[nucleated red blood cell]/100 %; and Unclassified Cell %) had been reported as not graded. *Blood Cell ID (Educational) ECI-01, 02, 03, 04, and 05 had been reported as not graded. b. 2023 Hematology /Coagulation third event *Vaginal Wet Preparation VA-03 had been reported as not graded. *Educational Blood Cell Identification (DIF) DF-03 (which included the following analytes Basophil %; Eosinophil %; Immature cell %; Lymphocyte %;

Lymphocyte, reactive %; Monocyte %, Neutrophil, band %; Neutrophil, segmented or band %; Neutrophil, segmented %, NRBC[nucleated red blood cell]/100 %; and Unclassified Cell %) had been reported as not graded. *Platelet estimate (DIF) DIF-03 had been reported as not graded. *Blood Cell ID (Educational) ECI-11, 12, 13, 14, and 15 had been reported as not graded. c. 2023 Chemistry Core second event *BNP (B-type natiuretic peptide) CM-06 had been reported as 454.3 pg/ml (picograms /milliliter). The acceptable range was 548.2-912.3 pg/ml. The analyte had been graded as unacceptable. *BNP CM-09 had been reported as 644.3 pg/ml. The acceptable range was 1001.9-1613.1 pg/ml. *Documentation of the investigation of the unacceptable results had been, "BNP CM-06 and CM-09 reran and was." There had been no documentation of any further investigation. *Creatine Kinase CH-08 had been reported as 87 U/L (units/liter). The acceptable range had been 42-80 U/L. The analyte had been graded as unacceptable. d. 2023 Microbiology first event *Molecular Bacti-Blood Acintobacter sp. BCP-04 had been reported as detected. The acceptable response was not detected. The analyte had been graded as unacceptable. *Molecular Bacti-Blood Acintobacter baumannii BCP-04 had been reported as detected. The acceptable response was not detected. The analyte had been graded as unacceptable. *Molecular Resistance Genes-Blood BCP-01, 02, and 03 had been reported as not graded for the following resistance genes (genes which confer resistance in bacteria to specific antibiotics) CTX-M, IMP, KPC. *Molecular Resistance Genes-Blood BCP-01, 02, 03, and 04 had been reported as not graded for the resistance gene mcr-1. *Molecular Resistance Genes-Blood BCP-01, 03, 04, 05 had been reported as not graded for the resistance gene mecA. *Molecular Resistance Genes-Blood BCP-01, 02, 03, 04, 05 had been reported as not graded for the resistance gene mecA/C. *Molecular Resistance Genes-Blood BCP-02 mecA had been reported as not detected. The acceptable response was detected. The analyte had been graded as unacceptable. e. 2023 Microbiology second event *Molecular Bacti-Blood BCP 06 Enterococcus sp. had been reported as not graded. *Molecular Bacti-Blood BCP-07 Listeria sp. had been resulted as not detected. The acceptable response was detected. The analyte had been graded as unacceptable. f. 2024 Hematology/Coagulation first event *Partial thromboplastin time (PTT) COA-01 had been resulted as 43 seconds. The acceptable range had been 25-35 seconds. The analyte had been graded as unacceptable. *PTT COA- 04 had been resulted as 53 seconds. The acceptable range had been 61-84 seconds. The analyte had been graded as unacceptable. *Body Fluid Cell Count-C polymorphonuclear cells % had been reported as not graded. *Educational Blood Cell Identification (DIF) DF-01 (which included the following analytes Basophil %; Eosinophil %; Immature cell %; Lymphocyte %; Monocyte %; and Neutrophil, segmented or band % had been reported as not graded. *Platelet estimate (DIF) DIF-01 had been reported as not graded. *RBC (red blood cell) Morphology (DIF) DIF-01 had been reported as not graded. *Blood Cell ID (Educational) ECI-01, 02, 03, 04, and 05 had been reported as not graded. g. 2024 Chemistry Core first event *Bilirubin, total CH-02, 03 and 05 had been reported as not graded. h. 2024 Chemistry Core Verification Comparative Evaluation first event *Troponin CM-01 was resulted as 19.69 ng/ml (nanograms/milliliter). The acceptable range had been 32.76-58.05 ng/ml. Documentation of the investigation of the unacceptable result had been "(testing personnel C) completed will follow up with him." There was no further documentation the unacceptable result had been investigated. i. 2024 Microbiology second event *Gram Stain GS-08 was reported as not graded. Review of the laboratory's PT reports revealed: *There had been no investigation of the unacceptable or ungraded results for the above listed samples to determine if the potential cause could have affected patient test results. *Technical consultant D had reviewed and initialed the evaluation reports for the PT testing events listed above. Review on 8/6 /24 of the laboratory's CMS form 209, Laboratory Personnel Report (CLIA), revealed

	technical consultant D was designated as the technical consultant for the laboratory. Review on 8/6/24 of the laboratory's Delegation of Responsibilities- Chamberlain policy, last updated 8/2/24, revealed: *Technical consultant D was designated as the technical consultant and technical supervisor. *6.2 Technical Consultant/Technical Supervisor responsibilities: 6.2.3.3. PT results are reviewed with the appropriate staff. 6.2.3.4. Corrective action for unsatisfactory PT results. Review on 8/6/24 of the laboratory's Proficiency Testing policy, last updated 7/28/2023, revealed: *"7. Evaluation of PT Agency Report A. The Laboratory Director/designee reviews all reports received back from the PT agency and alternative PT reports. 1) Investigation and review must be concluded within 30 days of receipt of summary score." *"D. How to Perform Self-Evaluation ... 2) Self-Evaluation is required on all ungraded challenges. a. Examples include, but are not limited to: I. PT challenges that were intended to be graded, but were not, for reasons such as: i. The laboratory submitted its results after the cut-off date ii. The laboratory did not submit results. iii. The laboratory did not complete the result form correctly iv. The laboratory's result was not graded because of a lack of consensus II. Educational PT challenges 3) Fill out the Ungraded Proficiency Test Challenges Form- Enterprise or document this same information on your proficiency testing results report. Results that do not agree with the majority or intended result will be investigated in the same manner as any unacceptable graded challenge." *"E. Evaluation of PT Failure 1. All proficiency failures must be evaluated and documented to determine the root cause of the failure." Review on 8/6/24 of technical consultant D's monthly visitation report dated 7/1/24 revealed: *She documented 3 ungraded total bilirubin specimens had been noted on the API 2024 Chemistry Core second event evaluation form and 2 unacceptable PTT results on the API 2024 Hematology/Coagulation first event evaluation form. *She did not document the lack of an investigation into the ungraded and unacceptable results. Interview on 8/6/24 at 9:25 AM with laboratory supervisor B revealed: *She confirmed that the documentation of the BNP and Troponin results was incomplete. *She had not been aware some of the investigations into unacceptable PT results had not been completed. *She had been unaware the ungraded results needed to be reviewed. *She did confirm that technical consultant D had made montly onsite visits. During these monthly visits, she would have reviewed the PT evaluation forms. *She confirmed that laboratory director A visited the facility once a year. At which time, he would sign all the PT attestation forms and review all corrective actions taken.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to ensure proficiency testing (PT) results had been reviewed, evaluated, and those activities documented for 9 of 24 PT events reviewed (American Proficiency Institute [API] 2023 Hematology/Coagulation first and third event; 2023 Chemistry Core second event; 2023 Microbiology first and second events; 2024 Hematology/Coagulation first event; 2024 Chemistry Core first event; 2024 Chemistry Core Verification Comparative Evaluation first event; and 2024 Microbiology second event). The failure to identify the potential cause of the unacceptable and ungraded results could have led to a failure to identify inaccurate patient test results. Findings include: 1.

Review on 8/6/24 of the API 2023 and 2024 PT event evaluations revealed: a. 2023 Hematology/Coagulation first event *Educational Blood Cell Identification DIF (manual differential- count of the various white blood cells present in the specimen) DF-01 (which included the following analytes Basophil %; Eosinophil %; Immature cell %; Lymphocyte %; Lymphocyte, reactive %; Monocyte %, Neutrophil, band %; Neutrophil, segmented or band %; Neutrophil, segmented %, NRBC[nucleated red blood cell]/100 %; and Unclassified Cell %) had been reported as not graded. *Blood Cell ID (Educational) ECI-01, 02, 03, 04, and 05 had been reported as not graded. *The PT evaluation report had been available for review on 4/18/23. *There was no documentation laboratory director A had reviewed the PT evaluation form. *The laboratory director had signed the attestation statement on 8/1/24. The attestation statement attests the PT specimens had been tested in the same manner as patient specimens. b. 2023 Hematology/Coagulation third event *Vaginal Wet Preparation VA-03 had been reported as not graded. *Educational Blood Cell Identification (DIF) DF-03 (which included the following analytes Basophil %; Eosinophil %; Immature cell %; Lymphocyte %; Lymphocyte, reactive %; Monocyte %, Neutrophil, band %; Neutrophil, segmented or band %; Neutrophil, segmented %, NRBC[nucleated red blood cell]/100 %; and Unclassified Cell %) had been reported as not graded. *Platelet estimate (DIF) DIF-03 had been reported as not graded. *Blood Cell ID (Educational) ECI-11, 12, 13, 14, and 15 had been reported as not graded. *The PT evaluation report had been available for review on 12/19/23. *Laboratory director A had reviewed and signed the PT evaluation report and PT attestation statement on 8/1 /24. c. 2023 Chemistry Core second event *BNP (B-type Natiuretic Peptide) CM-06 had been reported as 454.3 pg/ml (picograms/milliliter). The acceptable range was 548.2-912.3 pg/ml. The analyte had been graded as unacceptable. *BNP CM-09 had been reported as 644.3 pg/ml. The acceptable range was 1001.9-1613.1 pg/ml. *Documentation of the investigation of the unacceptable results had been, "BNP CM-06 and CM-09 reran and was." There had been no documentation of any further investigation. *Creatine Kinase CH-08 had been reported as 87 U/L (units/liter). The acceptable range had been 42-80 U/L. The analyte had been graded as unacceptable. *The PT evaluation report had been available for review on 6/27/23. *There was no documentation laboratory director A had reviewed the PT evaluation form. *The laboratory director had signed the attestation statement on 8/1/24. d. 2023 Microbiology first event *Molecular Bacti-Blood Acintobacter sp. BCP-04 had been reported as detected. The acceptable response was not detected. The analyte had been graded as unacceptable. *Molecular Bacti-Blood Acintobacter baumannii BCP-04 had been reported as detected. The acceptable response was not detected. The analyte had been graded as unacceptable. *Molecular Resistance Genes-Blood BCP-01, 02, and 03 had been reported as not graded for the following resistance genes (genes which confer resistance in bacteria to specific antibiotics) CTX-M, IMP, KPC. *Molecular Resistance Genes-Blood BCP-01, 02, 03, and 04 had been reported as not graded for the resistance gene mcr-1. *Molecular Resistance Genes-Blood BCP-01, 03, 04, 05 had been reported as not graded for the resistance gene mecA. *Molecular Resistance Genes-Blood BCP-01, 02, 03, 04, 05 had been reported as not graded for the resistance gene mecA/C. *Molecular Resistance Genes-Blood BCP-02 mecA had been reported as not detected. The acceptable response was detected. The analyte had been graded as unacceptable. *The PT evaluation report had been available for review on 3/21/23. *Laboratory director A had reviewed and signed the PT evaluation report and PT attestation statement on 8/1/24. e. 2023 Microbiology second event *Molecular Bacti-Blood BCP 06 Enterococcus sp. had been reported as not graded. *Molecular Bacti-Blood BCP-07 Listeria sp. had been resulted as not detected. The acceptable response was detected. The analyte had been graded as unacceptable. *The PT evaluation report had been available for review on 7/18/23. *Laboratory director A

	had reviewed and signed the PT evaluation report and PT attestation statement on 8/1 /24. f. 2024 Hematology/Coagulation first event *Partial thromboplastin time (PTT) COA-01 had been resulted as 43 seconds. The acceptable range had been 25-35 seconds. The analyte had been graded as unacceptable. *PTT COA- 04 had been resulted as 53 seconds. The acceptable range had been 61-84 seconds. The analyte had been graded as unacceptable. *Body Fluid Cell Count-C polymorphonuclear cells % had been reported as not graded. *Educational Blood Cell Identification (DIF) DF-01 (which included the following analytes Basophil %; Eosinophil %; Immature cell %; Lymphocyte %; Monocyte %; and Neutrophil, segmented or band % had been reported as not graded. *Platelet estimate (DIF) DIF-01 had been reported as not graded. *RBC (red blood cell) Morphology (DIF) DIF-01 had been reported as not graded. *Blood Cell ID (Educational) ECI-01, 02, 03, 04, and 05 had been reported as not graded. *The PT evaluation report had been available for review on 4/16/24. *Laboratory director A had reviewed and signed the PT evaluation report and PT attestation statement on 8/1/24. g. 2024 Chemistry Core first event *Bilirubin, total CH-02, 03 and 05 had been reported as not graded. *The PT evaluation report had been available for review on 2/20/24. *Laboratory director A had reviewed and signed the PT evaluation report and PT attestation statement on 8/1/24. h. 2024 Chemistry Core Verification Comparative Evaluation first event *Troponin CM-01 was resulted as 19.69 ng/ml (nanograms/milliliter). The acceptable range had been 32.76-58.05 ng /ml. Documentation of the investigation of the unacceptable result was "(testing personnel C) completed will follow up with him." There was no further documentation the unacceptable result had been investigated. *The PT evaluation report had been available for review on 2/20/24. *Laboratory director A had reviewed and signed the PT evaluation report and PT attestation statement on 8/1/24. i. 2024 Microbiology second event *Gram Stain GS-08 was reported as not graded. *The PT evaluation report had been available for review on 7/16/24. *Laboratory director A had not reviewed the PT evaluation report or signed the PT attestation statement as of the date of the survey. Review of the laboratory's PT reports revealed: *There had been no investigation of the unacceptable or ungraded results for the above listed samples to determine if the potential cause could have affected patient test results. *Laboratory director A had reviewed and initialed the evaluation reports for the PT testing events listed above with the exception of 2023 Hematology/Coagulation first event, 2023 Chemistry Core second event, and 2024 Microbiology second event. These events had not been documented as reviewed by laboratory director A. Review on 8/6/24 of the laboratory's Proficiency Testing policy, last updated 7/28/2023, revealed: *"Reporting of Results C. Sign the attestation statement. All testing personnel including those submitting the result to the proficiency agency must sign the attestation statement. When the attestation statement is complete have it signed by the director or designee. " *"7. Evaluation of PT Agency Report A. The Laboratory Director/designee reviews all reports received back from the PT agency and alternative PT reports. 1) Investigation and review must be concluded within 30 days of receipt of summary score." Review on 8/6/24 of the laboratory's Delegation of Responsibilities- Chamberlain policy, last revised 8/2/24, revealed: *"6.2.3.5. Laboratory Director reviews PT results." *There was no documentation of delegation of the duty of signing PT attestation statements documented in the policy. Interview on 8/6/24 at 12:40 PM with laboratory supervisor B revealed: *Laboratory director A would make an onsite visit once a year. During this visit he would sign the attestation statements, review PT corrective action forms and verify all required analytes had been enrolled in PT for the year. *On 8/1/24, laboratory supervisor B had to travel to Sioux Falls. She had brought the 2023 and 2024 API PT logbooks for laboratory director A to review and sign prior to the upcoming survey.

D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on record review and interview, the technical supervisor failed to evaluate the competency of one of five testing personnel (C), twice in their first year of employment, for their level of competency in performing testing completed on patient specimens. Findings include: 1. Review on 8/6/24 of testing personnel C's personnel file revealed he had been hired in February 2022. He had a competency assessment completed in 2/23. He had not had a second competency assessment completed until 4 /8/24. Review on 8/6/24 of the laboratory's Competency Assessment - South Region policy, last revised 1/29/24, revealed, "New lab personnel will be assessed for competency at 6 months and 1 year and annually thereafter." Interview on 8/6/24 at 8: 20 AM with laboratory supervisor B revealed the competency assessment was a continuous process. She was not aware a second competency had not been completed for testing personnel C.