Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0648034	(X3) Date Survey Completed 11/10/2020
Name of Provider or Supplier Sioux Center Health	**Street Address, City, State** 1101 9th Street Se, Sioux Center, 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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by laboratory personnel identifier #3 (refer to the Laboratory Personnel Report) at approximately 9: 50 am on 11/10/2020, the laboratory failed to perform a self evaluation of ungraded PT scores for three out of six PT testing events in 2019-2020 (2019 events 1 and 3 and 2020 event 1). The findings include: 1. For 2019 testing event 1, the laboratory received ungraded PT test scores for the following: *2019 Hematology and Coagulation 1st event- urine sediment (specimen US-02) *2019 Microbiology 1st event- susceptibility testing- ampicillin/sulbactrum (specimen UR-01) *2019 Microbiology 1st event- susceptibility testing- cefuroxime (specimen UR-01) 2. For 2019 testing event 3, the laboratory received ungraded PT test scores for the following: *2019 Microbiology 3rd event- stool culture (specimen SC-02) 3. For 2020 testing event 1, the laboratory received ungraded PT test scores for the following: *2020 Hematology and Coagulation 1st event- fecal leukocytes (specimen FW-01) 4. At the time of the survey, the laboratory did not have additional documentation or corrective action for the ungraded PT test scores.
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 review of proficiency testing (PT) records and confirmed by laboratory personnel identifier #3 (refer to the Laboratory Personnel Report) at approximately 9: 50 am on 11/10/2020, the laboratory failed to take and document corrective action for five unacceptable PT scores from four out of six PT testing events (2019 events 1 and 2 and 2020 events 1 and 3) in 2019-2020. The findings include: 1. For 2019 testing event 1, the laboratory received unacceptable PT test scores for the following: *2019 Hematology and Coagulation 1st event- blood cell identification (specimen BCL-05) 2. For 2019 testing event 2, the laboratory received unacceptable PT test scores for the following: *2019 Microbiology 2nd event- gram stain morphology (specimen GS-06) 3. For 2020 testing event 1, the laboratory received unacceptable PT scores for the following: *2020 Chemistry Core 1st event- phosphorus (specimens CH-04 and CH-05) 4. For 2020 testing event 3, the laboratory received unacceptable PT test scores for the following: *2020 Chemistry Core 3rd event- uric acid (specimen CH-12) 5. At the time of the survey, the laboratory did not have additional documentation or corrective action for the unacceptable PT test scores.