Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0703355	01/24/2019
Name of Provider or Supplier	**Street Address, City, State**	
Siouxland Community Health Center	1021 Nebraska Street, Sioux City, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by laboratory personnel #3 (refer to the Laboratory Personnel Report) at approximately 8:30 am on 1 /24/2019; the testing personnel and laboratory director failed to attest to the routine integration of PT samples into the patient workload for four out of six PT events events (2017 event 3, 2018 events 1, 2 and 3). The findings include: 1. For 2017 PT event 3, the testing personnel and laboratory director did not sign the attestation statements for chemistry or hematology. 2. For 2018 PT event 1, the testing personnel and laboratory director did not sign the attestation statements for immunology, chemistry and miscellaneous chemistry. The laboratory director did not sign the attestation statement for hematology. 3. For 2018 PT event 2, the testing personnel and laboratory director did not sign the attestation statements for immunology, chemistry, miscellaneous chemistry, hematology, and microbiology. 4. For 2018 PT event 3, the testing personnel and laboratory director did not sign the attestation statements for immunology, chemistry, hematology, and microbiology.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through

	493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's Individualized Quality Control Plan (IQCP) and confirmed by laboratory personnel identifier #3 (refer to Laboratory Personnel Report) at approximately 10:15 am on 01/24/2019, the laboratory failed to include as part of the IQCP for the Cepheid GeneXpert test system an IQCP quality control and quality assessment plan. The findings include: 1. In March 2018, the laboratory installed the Cepheid GeneXpert test system to perform Neisseria gonorrhea and Chlamydia testing. 2. The laboratory performed a risk assessment for the test system and intended to follow the manufacturer's instructions for performing quality controls. 3. At the time of the survey, the laboratory did not have a quality control or quality assessment plan as part of the IQCP.