Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0385251	02/07/2019
Name of Provider or Supplier	**Street Address, City, State**	
Family Health Care Of Siouxland-Indian Hills	2600 Outer Drive North, 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
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: A. Based on review of the laboratory's Individualized Quality Control Plan (IQCP) and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11:00 am on 02/07/2019, the laboratory failed to include a written quality assessment plan as part of the IQCP for the Siemens DCA Vantage test system (microalbumin). B. Based on review of the laboratory's Individualized Quality Control Plan (IQCP), quality control (QC) logs, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11: 00 am on 02/07/2019, the laboratory failed to perform two levels of microalbumin QC monthly for three out of four months (June, July, and August 2018) from 05/2018- 08 /2018. The findings include: 1. The laboratory's IQCP for microalbumin testing performed on the Siemens DCA Vantage test system stated that QC would be performed with each new lot number and shipment of tests and at least monthly. 2. The laboratory received a new lot number/shipment of tests (lot 0147028, expiration 02/28/20) and performed two levels of QC on 05/22/2018. 3. Personnel identifier #1 stated that the laboratory used the same lot number/shipment of tests from 05/22 /2018- 08/31/2018, but did not perform QC on that lot number in June, July, or August of 2018. 4. At the time of the survey, personnel identifier #1 confirmed that

	the laboratory only performed QC with each new lot number and shipment of tests but not at least monthly as stated in the IQCP.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of personnel records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 9:00 am on 02/07/2019, the laboratory director failed to ensure that prior to testing patient specimens, all testing personnel performing moderate complexity testing received the appropriate training for one out of one new testing personnel (personnel identifier #5) hired in 2017. The findings include: 1. Personnel identifier #5 began performing complete blood count (CBC) testing in October 2017. 2. Personnel identifier #1 stated that personnel identifier #5 only performed CBC testing in the laboratory and had been trained, but it had not been documented. 3. Personnel records for identifier #5 indicated that competency assessments for CBC testing were performed in April and October 2018. 4. At the time of the survey, laboratory personnel identifier #1 confirmed that the laboratory did not have documented training records available for personnel identifier #5.