Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0442444	01/17/2018
Name of Provider or Supplier	**Street Address, City, State**	
Piedmont Family Clinic	#1 Hals Plaza Drive, Piedmont, MO	

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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of chemistry proficiency testing (PT) record and interview with the technical consultant, the laboratory failed to review and evaluate unacceptable results for second PT event of 2016. Findings. 1. Review of chemistry PT records for second event 2016 revealed the laboratory obtained unacceptable results for total bilirubin (sample CH-07) and urea nitrogen (sample CH-08). 2. The laboratory did not have documentation to show review and evaluation of the unacceptable results. 3. Interview with the technical consultant on January 17, 2018 at 11;15 AM confirmed, the laboratory failed to review and evaluate the unacceptable PT results obtained for second chemistry event of 2016.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or

	control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the urinalysis procedure manual approved/ signed by the director on September 21, 2015 and currently in use, and interview with the technical consultant on January 17, 2018 at 10:00 AM confirmed, the manual did not include the operating speed of the urinalysis centrifuge required for processing urine for microscopic examination.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of chemistry calibration verification records and interview with the technical consultant, the laboratory failed to perform calibration verification procedures for the hemoglobin component of the HgbA1C test at least once every six months for 2016 and 2017 to verify the reportable range of the test system. Findings: 1. Review of calibration verification records for the HgBA1C test performed on the Dimension EXL 200 chemistry analyzer revealed the laboratory did not perform calibration verification procedures for the hemoglobin component to include at least a minimal value, mid-point value and maximum value near the upper limit at least once every six months to verify the reportable range of the complete test system. 2. Interview with the technical consultant on January 17, 2018 at 10:05 confirmed, the laboratory failed to perform calibration verification procedures for the hemoglobin component of the HgBA1C test for 2016 and 2017.

D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of verification procedures for the KX-21 N hematology analyzer and interview with the technical consultant on January 17, 2018 at 11:00 AM confirmed, the laboratory did not have documentation to show the director reviewed and approved verification procedures for the hematology analyzer in use for patient testing since 2008.